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Listing 16.2.1.1: Discontinued patients

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Treat- ment	Random No.	Site ID	Sex	Age	Date of with- drawal	Date of last IMP intake	Date of last subject data collected	Extent of completion [days]#	Reason for withdrawal	Date of death	Cause of death
ACI-91	004	1	MALE	75	15OCT2009	15OCT2009	29OCT2009	91	CONSENT WITHDRAWN		
	010	1	MALE	75	07NOV2009	06NOV2009	20NOV2009	109	CONSENT WITHDRAWN		
	032	8	FEMALE	69	07FEB2011	07FEB2011	07FEB2011	81	PATIENT NON-COMPLIANCE		
	043	12	MALE	68	11AUG2010	11AUG2010	17SEP2010	266	ADVERSE EVENT	12AUG2010	ASPIRATION PNEUMONIA
	055	5	FEMALE	72	28APR2010	30MAR2010	28APR2010	30	ADVERSE EVENT		
	057	1	FEMALE	69	08APR2011	06APR2011	08APR2011	232	CONSENT WITHDRAWN		
	066	16	MALE	82	21DEC2010	21DEC2010	09FEB2011	103	ADVERSE EVENT		
	067	16	FEMALE	62	31DEC2010	31DEC2010	08MAR2011	43	ADVERSE EVENT		
	080	13	FEMALE	70	01JUN2011	04MAR2011	01JUN2011	195	ADVERSE EVENT		
	097	12	MALE	72	16FEB2011	16FEB2011	20FEB2011	91	CONSENT WITHDRAWN		
Placebo	003	1	FEMALE	67	04FEB2010	04FEB2010	04FEB2010	252	CONSENT WITHDRAWN		

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach
Amount of days from date of visit 1 to date of withdrawal

Listing 16.2.1.1: Discontinued patients

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Treat- ment	Random No.	Site ID	Sex	Age	Date of with- drawal	Date of last IMP intake	Date of last subject data collected	Extent of completion [days]#	Reason for withdrawal
Placebo	020	5	MALE	53	24FEB2010		25FEB2010	2	CONSENT WITHDRAWN
	049	21	FEMALE	72	08SEP2011	08SEP2011	24NOV2011	316	ADVERSE EVENT
	065	16	MALE	59	16MAR2011	16MAR2011	21OCT2011	198	ADVERSE EVENT

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 16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach
 # Amount of days from date of visit 1 to date of withdrawal

Listing 16.2.2.1: Protocol deviations

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Major protocol deviations leading to exclusion from the Per-Protocol population

See documentation of BDRM

Listing 16.2.3.1: Patients excluded from efficacy analysis

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Treat- ment	Random No.	Site ID	Patient included in				Reason(s) for exclusion from PP
			Safety	ITT	PP	PK	
ACI-91	002	1	YES	YES	YES	YES	
	004	1	YES	YES	NO	YES	COMPLIANCE, DISCONTINUED PATIENT
	006	2	YES	YES	YES	YES	
	010	1	YES	YES	NO	YES	PROHIBITED MEDICATION, COMPLIANCE, DISCONTINUED PATIENT
	012	1	YES	YES	NO	YES	PROTOCOL DEVIATION, COMPLIANCE
	014	4	YES	YES	YES	YES	
	015	4	YES	YES	YES	YES	
	017	5	YES	YES	YES	YES	
	019	5	YES	YES	YES	YES	
	023	4	YES	YES	NO	YES	PROHIBITED MEDICATION
	027	20	YES	YES	YES	YES	
	030	8	YES	YES	NO	YES	PROHIBITED MEDICATION
	032	8	YES	YES	NO	YES	COMPLIANCE, DISCONTINUED PATIENT
	033	9	YES	YES	YES	YES	
	042	12	YES	YES	YES	YES	
	043	12	YES	YES	NO	YES	PROTOCOL DEVIATION, PROHIBITED MEDICATION, DISCONTINUED PATIENT
	046	11	YES	YES	NO	YES	PROHIBITED MEDICATION
	048	11	YES	YES	YES	YES	
	050	21	YES	YES	YES	YES	
	052	21	YES	YES	YES	YES	
	055	5	YES	YES	NO	YES	COMPLIANCE, DISCONTINUED PATIENT
	057	1	YES	YES	NO	YES	COMPLIANCE, DISCONTINUED PATIENT

For calculation of compliance number of dispensed tablets manually increased from 700 to 910 for Random No. 001 and 033 and from 910 to 1050 for Random No. 058

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.3.1: Patients excluded from efficacy analysis

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Treat- ment	Random No.	Site ID	Patient included in				Reason(s) for exclusion from PP
			Safety	ITT	PP	PK	
ACI-91	066	16	YES	YES	NO	YES	PROTOCOL DEVIATION, PROHIBITED MEDICATION, COMPLIANCE, DISCONTINUED PATIENT
	067	16	YES	YES	NO	YES	COMPLIANCE, DISCONTINUED PATIENT
	071	18	YES	YES	YES	YES	
	080	13	YES	YES	NO	YES	PROHIBITED MEDICATION, COMPLIANCE, DISCONTINUED PATIENT
	081	17	YES	YES	YES	NO	
	083	17	YES	YES	YES	YES	
	087	16	YES	YES	NO	YES	PROTOCOL DEVIATION
	089	5	YES	YES	YES	YES	
	093	17	YES	YES	YES	NO	
	097	12	YES	YES	NO	YES	COMPLIANCE, DISCONTINUED PATIENT
Placebo	001	1	YES	YES	YES	YES	
	003	1	YES	YES	NO	NO	COMPLIANCE, DISCONTINUED PATIENT
	005	2	YES	YES	YES	YES	
	009	1	YES	YES	YES	YES	
	011	1	YES	YES	YES	YES	
	013	4	YES	YES	YES	YES	
	016	4	YES	YES	YES	YES	
	018	5	YES	YES	YES	YES	
	020	5	NO	NO	NO	NO	COMPLIANCE, DISCONTINUED PATIENT
	024	4	YES	YES	YES	YES	
	028	20	YES	YES	YES	YES	

For calculation of compliance number of dispensed tablets manually increased from 700 to 910 for Random No. 001 and 033 and from 910 to 1050 for Random No. 058

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Listing 16.2.3.1: Patients excluded from efficacy analysis

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Treat- ment	Random No.	Site ID	Patient included in				Reason(s) for exclusion from PP
			Safety	ITT	PP	PK	
Placebo	029	8	YES	YES	NO	YES	PROHIBITED MEDICATION
	031	8	YES	YES	YES	YES	
	034	9	YES	YES	YES	YES	
	041	12	YES	YES	YES	YES	
	044	12	YES	YES	NO	YES	COMPLIANCE
	045	11	YES	YES	YES	YES	
	047	11	YES	YES	YES	YES	
	049	21	YES	YES	NO	NO	PROTOCOL DEVIATION, PROHIBITED MEDICATION, COMPLIANCE, DISCONTINUED PATIENT
	051	21	YES	YES	YES	YES	
	056	5	YES	YES	YES	YES	
	058	1	YES	YES	YES	YES	
	059	1	YES	YES	YES	YES	
	065	16	YES	YES	NO	YES	PROHIBITED MEDICATION, COMPLIANCE, DISCONTINUED PATIENT
	068	16	YES	YES	YES	YES	
	069	23	YES	YES	YES	YES	
	072	18	YES	YES	YES	YES	
	079	13	YES	YES	NO	YES	PROTOCOL DEVIATION
	082	17	YES	YES	YES	YES	
	084	17	YES	YES	YES	NO	
	086	21	YES	YES	YES	YES	
	088	16	YES	YES	NO	NO	PROHIBITED MEDICATION

For calculation of compliance number of dispensed tablets manually increased from 700 to 910 for Random No. 001 and 033 and from 910 to 1050 for Random No. 058

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Listing 16.2.4.1: Demographic data / informed consent

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Treat- ment	Random No.	Site ID	Date of screening visit	Date of birth	Age [YEARS]	Sex	Female status	Scree- ning Number	Infor- mation procedure performed	Date of patient informed consent	Date of caregiver informed consent
ACI-91	002	1	16APR2009	10OCT1953	55	FEMALE	CHILDBEARING POTENTIAL	01-003	YES	16APR2009	16APR2009
	004	1	17JUN2009	15DEC1933	75	MALE		01-005	YES	17JUN2009	17JUN2009
	006	2	25JAN2010	05JUN1940	69	MALE		02-004	YES	25JAN2010	25JAN2010
	010	1	25JUN2009	04MAY1934	75	MALE		01-006	YES	25JUN2009	25JUN2009
	012	1	17JUN2010	29JUL1933	76	MALE		01-011	YES	17JUN2010	17JUN2010
	014	4	07OCT2009	19MAY1933	76	MALE		04-002	YES	07OCT2009	07OCT2009
	015	4	21JAN2010	21AUG1933	76	FEMALE	POSTMENOPAUSAL	04-003	YES	21JAN2010	21JAN2010
	017	5	14JUL2009	02APR1935	74	MALE		05-001	YES	01JUL2009	01JUL2009
	019	5	18NOV2009	09JAN1933	76	MALE		05-003	YES	18NOV2009	18NOV2009
	023	4	01JUL2010	22FEB1947	63	MALE		04-005	YES	01JUL2010	01JUL2010
	027	20	30SEP2010	17OCT1943	66	FEMALE	POSTMENOPAUSAL	20-001	YES	30SEP2010	30SEP2010
	030	8	18MAR2010	13SEP1941	68	FEMALE	POSTMENOPAUSAL	08-002	YES	17FEB2010	18MAR2010
	032	8	08NOV2010	11NOV1940	69	FEMALE	POSTMENOPAUSAL	08-004	YES	08NOV2010	08NOV2010
	033	9	28OCT2009	15JUN1949	60	FEMALE	POSTMENOPAUSAL	09-001	YES	28OCT2009	28OCT2009
	042	12	16DEC2009	11JAN1936	73	FEMALE	POSTMENOPAUSAL	12-004	YES	16DEC2009	16DEC2009
	043	12	21OCT2009	10MAY1941	68	MALE		12-002	YES	21OCT2009	21OCT2009
	046	11	14DEC2009	09NOV1932	77	FEMALE	POSTMENOPAUSAL	11-002	YES	07DEC2009	14DEC2009
	048	11	17NOV2010	03AUG1940	70	MALE		11-006	YES	17NOV2010	17NOV2010
	050	21	06SEP2010	06DEC1937	72	FEMALE	POSTMENOPAUSAL	21-002	YES	06SEP2010	06SEP2010
	052	21	06SEP2010	29FEB1936	74	FEMALE	POSTMENOPAUSAL	21-004	YES	06SEP2010	06SEP2010
	055	5	08MAR2010	31OCT1937	72	FEMALE	POSTMENOPAUSAL	05-005	YES	08MAR2010	08MAR2010
	057	1	29JUL2010	17JUN1941	69	FEMALE	POSTMENOPAUSAL	01-012	YES	29JUL2010	29JUL2010

* values assessed at Visit 1 (Baseline, week 0)

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Listing 16.2.4.1: Demographic data / informed consent

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Treat- ment	Random No.	Site ID	Date of baseline visit	Race*	Body height* [cm]	Body weight* [kg]	Body Tempe- rature* [°C]	MMSE at baseline
ACI-91	002	1	23APR2009	CAUCASIAN	162	65	36.9	25
	004	1	16JUL2009	CAUCASIAN	170	60	36.6	20
	006	2	26FEB2010	CAUCASIAN	165	75	36.1	28
	010	1	21JUL2009	CAUCASIAN	175	71	36.4	23
	012	1	19JUL2010	CAUCASIAN	169	64	36.3	24
	014	4	02NOV2009	CAUCASIAN	173	93	36.6	24
	015	4	22FEB2010	CAUCASIAN	160	66	36.8	21
	017	5	05AUG2009	CAUCASIAN	172	82	36.5	24
	019	5	09DEC2009	CAUCASIAN	176	97	35.9	23
	023	4	20JUL2010	CAUCASIAN	175	82	37.0	22
	027	20	21OCT2010	CAUCASIAN	163	51	36.2	25
	030	8	25MAR2010	CAUCASIAN	157	61	36.5	20
	032	8	18NOV2010	CAUCASIAN	162	58	37.2	
	033	9	04NOV2009	CAUCASIAN	149	89	36.4	24
	042	12	14JAN2010	CAUCASIAN	175	58	37.0	19
	043	12	18NOV2009	CAUCASIAN	175	86	36.2	23
	046	11	11JAN2010	CAUCASIAN	160	55	35.4	19
	048	11	22NOV2010	CAUCASIAN	180	84	36.5	23
	050	21	27OCT2010	CAUCASIAN	150	56	34.7	23
	052	21	28OCT2010	CAUCASIAN	172	72	35.0	23
	055	5	29MAR2010	CAUCASIAN	168	73	36.4	22
	057	1	19AUG2010	CAUCASIAN	170	89	36.6	21

* values assessed at Visit 1 (Baseline, week 0)

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Listing 16.2.4.1: Demographic data / informed consent

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Treat- ment	Random No.	Site ID	Date of screening visit	Date of birth	Age [YEARS]	Sex	Female status	Scree- ning Number	Infor- mation procedure performed	Date of patient informed consent	Date of caregiver informed consent
ACI-91	066	16	09AUG2010	14JAN1928	82	MALE		16-001	YES	05AUG2010	05AUG2010
	067	16	02NOV2010	30JUN1948	62	FEMALE	POSTMENOPAUSAL	16-005	YES	01NOV2010	01NOV2010
	071	18	20OCT2010	24AUG1941	69	FEMALE	POSTMENOPAUSAL	18-001	YES	20OCT2010	20OCT2010
	080	13	08NOV2010	08JUL1940	70	FEMALE	SURGICALLY STERILIZED	13-003	YES	08NOV2010	08NOV2010
	081	17	04OCT2010	11JUN1932	78	MALE		17-001	YES	04OCT2010	04OCT2010
	083	17	26OCT2010	04JAN1939	71	FEMALE	POSTMENOPAUSAL	17-003	YES	26OCT2010	26OCT2010
	087	16	09NOV2010	09MAR1940	70	FEMALE	POSTMENOPAUSAL	16-006	YES	08NOV2010	08NOV2010
	089	5	19OCT2010	26OCT1943	66	FEMALE	POSTMENOPAUSAL	05-007	YES	05OCT2010	05OCT2010
	093	17	29NOV2010	07MAY1953	57	FEMALE	POSTMENOPAUSAL	17-005	YES	29NOV2010	29NOV2010
	097	12	27OCT2010	03JUL1938	72	MALE		12-005	YES	26OCT2010	27OCT2010
Placebo	001	1	02APR2009	27JUL1942	66	FEMALE	POSTMENOPAUSAL	01-002	YES	26MAR2009	26MAR2009
	003	1	07MAY2009	18JAN1942	67	FEMALE	POSTMENOPAUSAL	01-004	YES	07MAY2009	07MAY2009
	005	2	19MAY2009	05JUL1932	76	FEMALE	POSTMENOPAUSAL	02-002	YES	19MAY2009	19MAY2009
	009	1	06AUG2009	04MAR1936	73	FEMALE	POSTMENOPAUSAL	01-007	YES	06AUG2009	06AUG2009
	011	1	05NOV2009	02FEB1944	65	FEMALE	POSTMENOPAUSAL	01-009	YES	05NOV2009	05NOV2009
	013	4	17AUG2009	23AUG1928	80	FEMALE	POSTMENOPAUSAL	04-001	YES	17AUG2009	29JUL2009
	016	4	01FEB2010	16MAR1955	54	MALE		04-004	YES	01FEB2010	01FEB2010
	018	5	03NOV2009	26JUL1943	66	FEMALE	POSTMENOPAUSAL	05-002	YES	03NOV2009	03NOV2009
	020	5	27JAN2010	14MAR1956	53	MALE		05-004	YES	27JAN2010	27JAN2010
	024	4	16JUL2010	27NOV1936	73	MALE		04-006	YES	16JUL2010	16JUL2010
	028	20	18NOV2010	13APR1937	73	FEMALE	POSTMENOPAUSAL	20-002	YES	18NOV2010	18NOV2010
	029	8	26JAN2010	14MAR1934	75	FEMALE	SURGICALLY STERILIZED	08-001	YES	12JAN2010	26JAN2010

* values assessed at Visit 1 (Baseline, week 0)

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Listing 16.2.4.1: Demographic data / informed consent

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Treat- ment	Random No.	Site ID	Date of baseline visit	Race*	Body height* [cm]	Body weight* [kg]	Body Tempe- rature* [°C]	MMSE at baseline
ACI-91	066	16	09SEP2010	CAUCASIAN	160	80	36.2	19
	067	16	18NOV2010	CAUCASIAN	156	72	36.4	27
	071	18	09NOV2010	CAUCASIAN	161	59	36.4	21
	080	13	18NOV2010	CAUCASIAN	163	69	35.5	28
	081	17	14OCT2010	CAUCASIAN	163	62	36.7	19
	083	17	10NOV2010	CAUCASIAN	165	60	36.8	19
	087	16	29NOV2010	CAUCASIAN	163	64	36.5	26
	089	5	16NOV2010	CAUCASIAN	172	72	36.4	21
	093	17	02DEC2010	CAUCASIAN	165	65	36.7	
	097	12	17NOV2010	CAUCASIAN	175	89	37.1	18
Placebo	001	1	09APR2009	CAUCASIAN	155	71	36.8	18
	003	1	28MAY2009	CAUCASIAN	172	65	36.8	22
	005	2	04JUN2009	CAUCASIAN	160	74	36.9	25
	009	1	08SEP2009	CAUCASIAN	160	66	36.9	22
	011	1	26NOV2009	CAUCASIAN	164	60	36.5	22
	013	4	16SEP2009	CAUCASIAN	180	68	37.6	21
	016	4	01MAR2010	CAUCASIAN	175	69	36.9	26
	018	5	23NOV2009	CAUCASIAN	158	63	36.2	19
	020	5	22FEB2010	CAUCASIAN	163	71	36.7	
	024	4	16AUG2010	CAUCASIAN	178	89	36.6	18
	028	20	26NOV2010	CAUCASIAN	161	64	35.1	22
	029	8	29JAN2010	CAUCASIAN	162	70	36.4	24

* values assessed at Visit 1 (Baseline, week 0)

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Listing 16.2.4.1: Demographic data / informed consent

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Treat- ment	Random No.	Site ID	Date of screening visit	Date of birth	Age [YEARS]	Sex	Female status	Scree- ning Number	Infor- mation procedure performed	Date of patient informed consent	Date of caregiver informed consent
Placebo	031	8	06MAY2010	02MAR1952	58	MALE		08-003	YES	11MAR2010	11MAR2010
	034	9	24FEB2010	26MAY1936	73	FEMALE	POSTMENOPAUSAL	09-002	YES	24FEB2010	24FEB2010
	041	12	23SEP2009	21JUN1930	79	MALE		12-001	YES	07SEP2009	23SEP2009
	044	12	04NOV2009	05FEB1937	72	FEMALE	POSTMENOPAUSAL	12-003	YES	28OCT2009	28OCT2009
	045	11	07DEC2009	06JAN1940	69	MALE		11-001	YES	07DEC2009	07DEC2009
	047	11	12JUL2010	29DEC1931	78	MALE		11-004	YES	12JUL2010	12JUL2010
	049	21	06SEP2010	14DEC1937	72	FEMALE	POSTMENOPAUSAL	21-001	YES	06SEP2010	06SEP2010
	051	21	06SEP2010	06MAY1931	79	FEMALE	POSTMENOPAUSAL	21-003	YES	06SEP2010	06SEP2010
	056	5	31MAR2010	16APR1935	74	FEMALE	POSTMENOPAUSAL	05-006	YES	18MAR2010	18MAR2010
	058	1	06DEC2010	28FEB1938	72	MALE		01-014	YES	06DEC2010	06DEC2010
	059	1	27DEC2010	09MAY1942	68	MALE		01-015	YES	27DEC2010	27DEC2010
	065	16	10AUG2010	11APR1951	59	MALE		16-002	YES	20JUL2010	20JUL2010
	068	16	26OCT2010	23MAR1933	77	MALE		16-003	YES	25OCT2010	25OCT2010
	069	23	24NOV2010	25SEP1941	69	MALE		23-002	YES	24NOV2010	24NOV2010
	072	18	01DEC2010	27AUG1936	74	FEMALE	POSTMENOPAUSAL	18-002	YES	01DEC2010	01DEC2010
	079	13	19JUL2010	15JAN1949	61	FEMALE	POSTMENOPAUSAL	13-001	YES	19JUL2010	19JUL2010
	082	17	06OCT2010	27MAR1932	78	MALE		17-002	YES	06OCT2010	06OCT2010
	084	17	08NOV2010	31OCT1928	82	FEMALE	POSTMENOPAUSAL	17-004	YES	08NOV2010	08NOV2010
	086	21	04OCT2010	04SEP1930	80	FEMALE	POSTMENOPAUSAL	21-007	YES	04OCT2010	04OCT2010
	088	16	30NOV2010	24FEB1948	62	FEMALE	POSTMENOPAUSAL	16-007	YES	29NOV2010	29NOV2010

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Listing 16.2.4.1: Demographic data / informed consent

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Treat- ment	Random No.	Site ID	Date of baseline visit	Race*	Body height* [cm]	Body weight* [kg]	Body Tempe- rature* [°C]	MMSE at baseline
Placebo	031	8	20MAY2010	CAUCASIAN	164	67	36.9	27
	034	9	18MAR2010	CAUCASIAN	156	61	35.9	18
	041	12	09OCT2009	CAUCASIAN	183	90	37.5	23
	044	12	02DEC2009	CAUCASIAN	163	79	36.5	22
	045	11	21DEC2009	CAUCASIAN	181	82	36.2	23
	047	11	02AUG2010	CAUCASIAN	175	76	36.5	26
	049	21	27OCT2010	CAUCASIAN	165	69	35.3	22
	051	21	28OCT2010	CAUCASIAN	164	85	34.9	24
	056	5	21APR2010	CAUCASIAN	158	58	36.3	26
	058	1	27DEC2010	CAUCASIAN	171	69	36.7	
	059	1	29DEC2010	CAUCASIAN	178	85	36.2	
	065	16	30AUG2010	CAUCASIAN	176	104	36.3	18
	068	16	22NOV2010	CAUCASIAN	176	83	35.4	26
	069	23	07DEC2010	CAUCASIAN	171	95	36.5	24
	072	18	21DEC2010	CAUCASIAN	160	71	36.0	18
	079	13	06AUG2010	CAUCASIAN	161	76	36.6	19
	082	17	14OCT2010	CAUCASIAN	175	80	36.8	23
	084	17	17NOV2010	CAUCASIAN	165	70	36.8	22
	086	21	28OCT2010	CAUCASIAN	168	65	35.0	23
	088	16	09DEC2010	CAUCASIAN	165	65	36.4	24

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Listing 16.2.4.2: Study indication

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Treat- ment	Random No.	Site ID	Actual day	Visit date	Year of onset of Alzheimer	Familial history	Specification
ACI-91	002	1	1	23APR2009	2008	NO	
	004	1	1	16JUL2009	2008	YES	MOTHER AND GRANDMOTHER: ALZHEIMER DISEASE
	006	2	1	26FEB2010	2009	NO	
	010	1	1	21JUL2009	2006	NO	
	012	1	1	19JUL2010	2008	NO	
	014	4	1	02NOV2009	2007	YES	BOTH PARENTS OF PATIENT HAD DEMENTIA WITH LATE ONSET, WITH NO HISTORY OF CEREBROVASCULAR DISEASE (PRB. ALZHEIMER DISEASE)
	015	4	1	22FEB2010	2003	YES	THE MOTHER OF THE PATIENT HAD DEMENTIA WITHOUT A HISTORY OF STROKE
	017	5	1	05AUG2009	2008	NO	
	019	5	1	09DEC2009	2009	NO	
	023	4	1	20JUL2010	2007	NO	
	027	20	1	21OCT2010	2009	YES	BROTHER, AUNT, MOTHER
	030	8	1	25MAR2010	2009	NO	
	032	8	1	18NOV2010	2009	NO	
	033	9	1	04NOV2009	2006	NO	
	042	12	1	14JAN2010	2007	YES	PATIENT'S MOTHER HAD AD
	043	12	1	18NOV2009	2006	NO	
	046	11	1	11JAN2010	2006	NO	
	048	11	1	22NOV2010	2008	YES	MOTHER OF PATIENT WITH DEMENTIA
	050	21	1	27OCT2010	2009	NO	
	052	21	1	28OCT2010	2003	YES	COUSIN
	055	5	1	29MAR2010	2010	NO	

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Listing 16.2.4.2: Study indication

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Treat- ment	Random No.	Site ID	Actual day	Visit date	Year of onset of Alzheimer	Familial history	Specification
ACI-91	057	1	1	19AUG2010	2010	YES	MOTHER AND 4 SIBLINGS OF THE MOTHER AND 1 COUSIN OF THE PATIENT
	066	16	1	09SEP2010	2009	NO	
	067	16	1	18NOV2010	2005	NO	
	071	18	1	09NOV2010	2005	YES	MOTHER, FATHER, BROTHER
	080	13	1	18NOV2010	2008	YES	MOTHER AND FATHER HAD SUFFERED FROM A SENILE DEMENTIA
	081	17	1	14OCT2010	2001	YES	BOTH SISTERS OF PATIENT DIED ON AD
	083	17	1	10NOV2010	2005	YES	MOTHER OF PAT.
	087	16	1	29NOV2010	2006	NO	
	089	5	1	16NOV2010	2010	NO	
	093	17	1	02DEC2010	2005	YES	MOTHER FROM PAT, SHE IS IN A NURSING HOME
Placebo	097	12	1	17NOV2010	2007	YES	PATIENT'S MOTHER HAD AD
	001	1	1	09APR2009	2005	NO	
	003	1	1	28MAY2009	2008	NO	
	005	2	1	04JUN2009	2007	NO	
	009	1	1	08SEP2009	2008	NO	
	011	1	1	26NOV2009	2008	NO	
	013	4	1	16SEP2009	2006	NO	
	016	4	1	01MAR2010	2009	NO	
	018	5	1	23NOV2009	2005	NO	
	020	5	1	22FEB2010	2005	YES	SISTER ALZHEIMER DISEASE
	024	4	1	16AUG2010	2005	NO	
	028	20	1	26NOV2010	2009	NO	
	029	8	1	29JAN2010	2009	NO	

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Listing 16.2.4.2: Study indication

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Treat- ment	Random No.	Site ID	Actual day	Visit date	Year of onset of Alzheimer	Familial history	Specification
Placebo	031	8	1	20MAY2010	2009	NO	
	034	9	1	18MAR2010	2007	NO	
	041	12	1	09OCT2009	2006	NO	
	044	12	1	02DEC2009	2007	NO	
	045	11	1	21DEC2009	2007	NO	
	047	11	1	02AUG2010	2008	NO	
	049	21	1	27OCT2010	2002	NO	
	051	21	1	28OCT2010	2009	YES	BROTHER OF PATIENT
	056	5	1	21APR2010	2009	NO	
	058	1	1	27DEC2010	2009	NO	
	059	1	1	29DEC2010	2010	NO	
	065	16	1	30AUG2010	2006	YES	MOTHER'S MOTHER
	068	16	1	22NOV2010	2007	NO	
	069	23	1	07DEC2010	2010	NO	
	072	18	1	21DEC2010	2005	YES	MOTHER
	079	13	1	06AUG2010	2006	NO	
	082	17	1	14OCT2010	2002	YES	UNCLE OF PAT.
	084	17	1	17NOV2010	2009	NO	
	086	21	1	28OCT2010	2007	NO	
	088	16	1	09DEC2010	2007	YES	MOTHER

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Listing 16.2.4.3.1: Medical and surgical history other than AD

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	002	1	-7	16APR2009	DEPRESSION	2007-11-22	YES	YES
	004	1	-29	17JUN2009	HYPERURICAEMIA	1987	YES	YES
	006	2	-32	25JAN2010	ARTERIAL HYPERTENSION	2005	YES	YES
	010	1	-26	25JUN2009	DEPRESSION	2003-10	YES	YES
					HIGH BLOOD PRESSURE	2008-07-09	YES	YES
					TRANSURETHRAL RESECTION OF PROSTATIC GLAND	2006-03	NO	
	012	1	-32	17JUN2010	ALZHEIMER'S DISEASE	2008-12	YES	YES
					MYOCARDIAL INFARCTS	1973	NO	
					TEMPORAL ASTERITIS	2004	NO	
					DEPRESSION	2007-01	NO	
					ARTERIAL HYPERTENSION	2008-07	NO	
					LUMBO ISCHIALGIA RIGHT	2010-04-01	YES	NO
					SPONDYLOLISTHESIS L5/S1	2010-05-03	YES	NO
					LWS-SKOLIOSIS RIGHT KONVEX	2010-05-03	YES	NO
					SPONDYLOSIS HYPERASTETICA	2010-05-03	YES	NO
					THORACOLUMBAL			
					HEPATITIS B INFECTION	2009-11-19	NO	
	014	4	-26	07OCT2009	HEPATITIS	1955	NO	

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Listing 16.2.4.3.1: Medical and surgical history other than AD

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	014	4	-26	07OCT2009	CATARACT SURGERY	1995	NO	
					CARPAL-TUNNEL-SYNDROM - SUGERY (RIGHT HAND)	1996	NO	
					COMMOTIO CEREBRI I (FIRST DEGREE)	2002	NO	
					PROSTATA HYPERPLASIA SURGERY	2003	NO	
					ARTHROSIS OF RIGHT KNEE	2006	YES	NO
					B12-HYPOVITAMINOSE (SUBSTITUTION)	2009-06	NO	
	015	4	-32	21JAN2010	ARTERIAL HYPERTENSION	2003	YES	YES
					HYPERCHOLESTERINEMA	2005-01	YES	YES
					PYROSIS	2008-12	YES	YES
					MOOD DISORDER (DEPRESSEION)	2002	NO	
	017	5	-22	14JUL2009	KNEE ENDOPROTHESIS LEFT LEG	2001-07-01	YES	NO
					GOITER	2002-01-01	NO	
					ADENOMA OF PROSTATA (ENUKLATION)	2003-11-25	NO	
					ART. HYPERTONUS	2007-01-01	YES	YES
					HYPERURIKEMIA	1966-01-01	YES	YES
					HYPERCHOLESTERINAEMIA	2009-04-01	YES	YES
					DEPRESSION	2008-09-01	YES	YES
					INCREASE SWEATING, ORIGIN UNKNOWN	2009-04-14	YES	NO
	019	5	-21	18NOV2009	ARTERIAL HYPERTENSION	2001	YES	YES
					HYPERCHOLESTERINEMIA	2001	YES	YES

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Listing 16.2.4.3.1: Medical and surgical history other than AD

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	019	5	-21	18NOV2009	HYPERPLASIA OF PROSTATE	2004	YES	YES
					CORONARY HEART DISEASE, STENT-IMPLANTATION	2003	YES	YES
					TBC-INFECTION	1956	NO	
					HYPERURICAEMIA	1999	YES	YES
	023	4	-19	01JUL2010	DISCUSPROLAPS S4/5	1991	NO	
					DISCUSPROLAPS C5/6	2006	YES	NO
	027	20	-21	30SEP2010	TOTAL HYSTERECTOMY	1992	NO	
					HYPERLIPIDEMIA	1990	YES	NO
					ELEVATED LEUKOCYTES	2010-09-30	YES	NO
	030	8	-7	18MAR2010	THYROID RESECTION	1990	NO	
					THYROID HYPERFUNCTION	1990	YES	YES
					OSTEOPOROSIS	2008	YES	YES
					SECTIO	1960	NO	
					SECTIO	1961	NO	
					SECTIO	1963	NO	
					SECTIO	1972	NO	
					MILD CEREBRAL MICROANGYOPATHY	2009-12	YES	YES
					MYOPIA	1960	YES	NO
					SECTION OF A PART OF GASTRIC DUE TO ULCERA	1990	NO	

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Listing 16.2.4.3.1: Medical and surgical history other than AD

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	030	8	-7	18MAR2010	MAMMA ADENOMA RESECTION	1995	NO	
					SYNCOPE	2009	NO	
					VERTIGO	2005	YES	YES
					NAUSEA	2005	YES	YES
					FEELING OF COLDNESS	2009-06	YES	NO
					SINUSBRADYCARDIA	2010	YES	NO
					CARPALTUNNELSYNDROME	2000	NO	
	032	8	-10	08NOV2010	RECURRENT STOMACHE PAIN	1950	YES	YES
					HYPERCHOLESTERINEMIA	2010-01-05	YES	NO
					MYOPIA	1990	YES	NO
					HOT FLASH SINCE MENOPAUSE	2000	YES	YES
					INSOMNIA	2010-01	YES	YES
					EOSINOPHILE GRANULOCYTOPENIA	2010-11-08	YES	NO
	033	9	-7	28OCT2009	ARTERIAL HYPERTENSION	2004	YES	YES
					DEPRESSION	2006-09	YES	YES
					HYPOTHYROIDISM	2004	YES	YES
	042	12	-29	16DEC2009	HYPERTONUS	2008	YES	YES
					HYPERCHOLESTERINAEMIA	2008	YES	YES
	043	12	-28	21OCT2009	HYPERTONUS	1991	YES	YES
					DIABETES MELLITUS	2006	YES	YES

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Listing 16.2.4.3.1: Medical and surgical history other than AD

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	043	12	-28	21OCT2009	CATARACT SURGERY BOTH SIDES	2009-03	NO	
	046	11	-28	14DEC2009	FUSION LWK 5/6 FOR CHRONICAL BACK PAIN	2002-10	YES	YES
					MILD TO MODERATE DEPRESSION	2006	YES	YES
					HYPERCHOLESTERINEMIA	1980	YES	NO
					PROLONGATED QTC TIMES	2009-03-27	YES	NO
					ELEVATED CREATININE	2009-12-14	YES	NO
					ELEVATED PROTEINE (URINE)	2009-12-14	NO	
					ELEVATED UREA	2009-12-14	YES	NO
	048	11	-5	17NOV2010	PROSTATAHYPOPLASIEA	2008	YES	YES
					HYPERTENSION	2000	NO	
					BORRELIA INFECTION	1992	NO	
					HYPERCHOLESTERINAMIA	2009-10	YES	YES
	050	21	-51	06SEP2010	DEPRESSION	2009-10-28	YES	YES
					CHOLELITHIASIS SURGERY	2004	NO	
					NON CORONARY NEGATIVE TIN LEAD 3	2010-09-06	NO	
					RECURRING HEAD ACHE	2010-07-28	YES	NO
					TINNITUS	2000-07-13	YES	NO
					HEARING LOSS	1995	YES	NO
					APOPLEXY OF THE RIGHT INDEX FINGER	1994-10-11	NO	
					SARCOIDOSIS	1969	YES	NO

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Listing 16.2.4.3.1: Medical and surgical history other than AD

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	050	21	-51	06SEP2010	VARICOSE VEINS	1994-10-11	YES	NO
					HYPOCHONDRIA	2000	YES	NO
					POSITIVE LABORATORY RESULT OF BORRELIA BURGDORFERI	2000-06-06	YES	NO
					POSITIVE LABORATORY RESULT OF CHLAMYDIA	2000-06-06	YES	NO
	052	21	-52	06SEP2010	STEATOSIS HEPATIS I	2008-04-16	YES	NO
					CALCIFIED MENINGIOMA	2001-12-18	YES	NO
					VASCULAR ENCEPHALOPATHY	2003-05-02	YES	NO
					POLYNEUROPATHY DISTAL	2003-05-02	YES	NO
					DRY AGE-RELATED MACULAR DEGENERATION	2008-04-16	YES	NO
					ATROPHIC GASTRITIS, HELIOBACTER PYLORI	2008-06-09	NO	
					SMALL AXIAL HIATUS HERNIA	2008-06-09	YES	NO
					REFLUX ESOPHAGITIS I	2008-06-09	YES	NO
					MILD COGNITIVE IMPAIRMENT	2003-06-06	YES	YES
					FOLIC ACID DEFICIENCY	2010-09-07	NO	
					VITAMIN B12 DEFICIENCY	2010-09-07	YES	YES
					SUBCORTICAL ENCEPHALOPATHY	2003-09-24	YES	NO
	055	5	-21	08MAR2010	KIDNEY EXCISION AFTER KIDNEY-TBC	2000	NO	
					APPENDECTOMY	1960	NO	

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	055	5	-21	08MAR2010	HYSTERECTOMY	1990	NO	
					PAIN IN RIGHT SHOULDER AFTER FALL	2010-03-01	YES	NO
	057	1	-21	29JUL2010	MAMMA CARCINOMA RIGHT WITH RESECTION AND RADIOTHERAPY	1995	NO	
					PSORIASIS	2005	YES	YES
					ARTERIAL HYPERTENSION	2009	YES	YES
					CARPALTUNNELSYNDROME RIGHT	2007	NO	
					DEPRESSION	2010-03	YES	YES
					INCONTINENCE OF URINE	2009	YES	NO
					INCONTINENCE OF FECAL	2009	YES	NO
	066	16	-31	09AUG2010	DIAB. MELLITUS	1990	YES	YES
					ART. HYPERTENSION	2000	YES	YES
					HYPOTHYREOSIS	2008	YES	YES
					MILD AGGRESSIV BEHAVIOR	2009	YES	NO
	067	16	-16	02NOV2010	AD	2005	YES	YES
					DEPRESSION (MDE)	2008-10	YES	YES
					MIGRAINE	2006	YES	NO
					HERNIATED VERTEBRAL DISC	2005	YES	NO
					SCOLIOSIS	1958	YES	NO
					OP CARPAL TUNNEL SYNDROME	2007-05-10	NO	

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	071	18	-20	20OCT2010	DEPRESSIVE DISORDER	2009-01	NO	
					HYPOTHYROIDISM	1961	YES	YES
					HYPERTHYROIDISM	1961	NO	
					HYPERCHOLESTERINAEMIA	2008-03	YES	YES
					REACTION OF ANXIETY	2009-07-28	YES	YES
					HYPERTENSION	2005	YES	YES
	080	13	-10	08NOV2010	APPENDECTOMY	1961	NO	
					HYSTERECTOMY DUE TO UTERINE PROLAPSE	1968	NO	
					DIVERTICULOSIS	2005	YES	NO
					DEPRESSION	2008	YES	YES
	081	17	-10	04OCT2010	HYPERTENSION	2003	YES	YES
					HYPACUSIS	2003	YES	NO
					PROSTATAHYPERTROPHY	2002	YES	NO
					HYPERCHOLESTERINEMIA	2002	YES	NO
	083	17	-15	26OCT2010	HEART DISEASE	1992	YES	YES
					STENT IMPLANTATION	1997	NO	
					STENT IMPLANTATION	2001	NO	
					ARTERIAL HYPERTONUS	2000	YES	YES
					HYPERCHOLESTEROLEMIA	1998	YES	YES
					HYPERALDOSTEROISM	1939	YES	YES

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
ACI-91	087	16	-20	09NOV2010	ART. HYPERTENSION DIAB. MELL.	1998 1998	YES YES	YES YES
	089	5	-28	19OCT2010	ARTERIAL HYPERTENSION KNEE ARTHROSIS INCONTINENCE	2007 2006 2010	YES YES YES	YES NO YES
	093	17	-3	29NOV2010	CHOLECYSTECTOMY DYSLIPOPROTEINEMIA	1980 2007-04-12	NO YES	NO NO
	097	12	-21	27OCT2010	HYPERTHYREOSIS CATARACT BOTH SIDES INGUINAL HERNIATION HYPERCHOLESTERINEMIA	2006 2009 2006 2003	YES NO NO YES	YES YES YES YES
Placebo	001	1	-7	02APR2009	HYPEROPIA BILATERAL	1997	YES	YES
					TONSILLECTOMY	1954	NO	
					REFLUXOESOPHAGITIS	2001	YES	YES
					STRUMECTOMY	1996	YES	YES
					HYPERCHOLESTEROLAEMIA	2005-07	YES	YES
					DELIVERY BY CAESARIAN SECTION	1969	NO	
					MYOMA	2002	YES	NO
					KNEE ARTHROSCOPY (MENISCOPATHIE) DEPRESSION	2002 2005-09	NO YES	NO YES

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Placebo	001	1	-7	02APR2009	LEFT BUNDLE BRANCH BLOCK	2008-08-04	YES	NO
	003	1	-21	07MAY2009	DEPRESSION	2009-03-02	YES	YES
					OSTEOPOROSIS	2003	YES	YES
					MILD LOCAL EXANTHEMA CAUSED BY RIVASTIGMIN TAPE	2009-01-08	YES	NO
	005	2	-16	19MAY2009	ANKLE OPERATION AFTER TRAUMA	1990	NO	
					SHOULDER OPERATION AFTER TRAUMA	1995	NO	
					ARTERIAL HYPERTENSION	2005	YES	YES
	009	1	-33	06AUG2009	INSULINDEPENDENT DIABETES MELLITUS	1988	YES	YES
					STRUMECTOMY	1958	YES	YES
					HYPERLIPIDAEMIA	2008-07	YES	YES
	011	1	-21	05NOV2009	DEPRESSION	2007-01	YES	YES
					HYPERCHOLESTERINAEMIA	2007-05	YES	NO
					THYROIDECTOMY BECAUSE OF THYROID CARCINOMA	1990-11	YES	YES
					PILMONARY SARCOIDOSIS	1976	NO	
					CATARACT SURGERY	2009-09-30	YES	YES
					HIGH BLOOD PRESSURE	1990	YES	YES
	013	4	-30	17AUG2009	MIGRAINE	1955	NO	

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Placebo	013	4	-30	17AUG2009	HYSTERECTOMY	1965	NO	
					VARICOSIS SURGERY	2004	NO	
					FRACTURE OF RIGHT CLAVICLE	2006-10	NO	
					HYPERHOMOCYSTEINEMIA	2006-11-17	NO	
					SLIGHT ABNORMAL TSH VALUE	2006-11-17	NO	
					SLIGHT ANEMIA	2009-07-08	YES	NO
					ECG-ABNORMALITIES (T-NEGATIVATION ON V2)	2008-07-17	YES	NO
					MUSCLE CRAMPS OF THE LEGS	2006	YES	YES
	016	4	-28	01FEB2010	B12 - DEFICIENCY	2009-05-11	YES	YES
					HEAD TRAUMA (AT AGE 18)	1973	NO	
					MIGRAINE	1968	YES	NO
					HYPERCHOLESTERINEMIA	2009-05-11	YES	YES
					VISUS DEFICIENCY SINCE BIRTH	1955	YES	NO
					HYPERHOMOCYSTEINEMIA	2009-05-11	NO	
	018	5	-20	03NOV2009	DEPRESSION	2008-08-28	YES	YES
					HYPERTENSION	2003-06	YES	YES
					HYPOTHYRIOSIS	2002-08	YES	YES
					POSTMENOPAUSAL DISCOMFORT	2009-01	YES	YES
	020	5	-26	27JAN2010	DIABETES TYPE I	1990	YES	YES
					HYPERCHOLESTERINEMIA	2005	YES	YES

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
Placebo	020	5	-26	27JAN2010	ASTHMA BRONCHIALE	2005	YES	YES
	024	4	-31	16JUL2010	HYPERCHOLESTERINEMIA	2008-11	YES	YES
					ART. HYPERTENSION	2008-11	YES	YES
					THYROID GLAND INSUFFICIENCY	2008	YES	YES
					HYPERHOMOZYSTHEINEMIA	2009-01-22	NO	
					HEAD INJURY	1954	NO	
					LUMBAR DISCUS PROLAPS SURGERY	2008-06	NO	
					KNEE JOINT SURGERY	1995	NO	
					KNEE JOINT SURGERY	1998	NO	
					SHOULDER JOINT SURGERY	1999	NO	
					RIGHT BUNDLE BRANCH BLOCK	2010-07-16	YES	NO
					CATARACT LEFT EYE	2010	NO	
	028	20	-8	18NOV2010	N. MAMMAE RIGHT, ST.P. MASTECTOMIA	1999	NO	
					ARTERIAL HYPERTENSION	1999	YES	NO
					CRAMPS IN THE CALF	2009	YES	YES
	029	8	-3	26JAN2010	DIABETES MELLITUS TYP II	2007	YES	YES
					ESSENTIELLE HYPERTENSION	1993	YES	YES
					MIXED HYPERLIPIDEMIA	2008-04	YES	YES
					HYPOTHYREOSIS	1993	YES	YES
					ZOSTER	1940	NO	
					ABLATION OF APPENDIX	1975	NO	

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
Placebo	029	8	-3	26JAN2010	HYSTERECTOMY	1975	NO	
					MYOPIA (WEAR GLASSES)	1980	YES	NO
					HYPERURICEMIA	1941	YES	YES
					RECURENT HEADACHE	1991	YES	YES
					RECURRENT STOMACHE PAIN	1961	YES	YES
	031	8	-14	06MAY2010	TONSELLEKTOMIA	1964	NO	
					HYPEROPIE	1990	YES	NO
					HYPERCHOLESTERINEMIA	2000	YES	YES
					PERTUSSIS	1961	NO	
	041	12	-16	23SEP2009	PROSTATE SURGERY	2007	NO	
					CEREBRAL ISCHAEMIA	1989	NO	
					ARTHROSCOPIA	2009-08	NO	
					KNEE PAIN	2009-07	YES	YES
					VISUS DEFICIENCY	1992	YES	NO
					AUDITORY DEFICIENCY	2000	YES	NO
					ONYCHOMYCOSIS BOTH FEET	2009-09	YES	NO
	044	12	-28	04NOV2009	HYPERTONUS	2002	YES	YES
					HYPERCHOLESTERINAEMIA	2007	YES	YES
					HYPERURICAEMIA	2007-11	YES	YES
	045	11	-14	07DEC2009	HYPERTONIA	2000	YES	YES

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
Placebo	045	11	-14	07DEC2009	HYPERCHOLESTERINEMIA	2000	YES	YES
					ARTHROSIS OF FINGER JOINTS	1992	YES	NO
					SLEEP APNOE SYNDROM	2007	YES	NO
	047	11	-21	12JUL2010	CORONARY HEART DISEASE WITH STENT (RIVA-PCTA)	2005-02	NO	
					HYPERTENSION	2005-02	YES	YES
					THROMBOSIS EYE RIGHT	2005	NO	
					PRESBYAKUSIS	2003	YES	NO
					HYPERCHOLESTERINEMIA	2005	YES	YES
					HYPOTHYREOSIS	2009-08	YES	YES
					THROMBOPENIE	2007-09	NO	NO
					DEPRESSION	2006-10-16	NO	NO
					HYPOVITAMINOSIS	2009-08	YES	YES
	049	21	-51	06SEP2010	BEHAVIOURAL DISEASE, AGGRESSIVENESS DISTURBANCE	2006-11-09	YES	YES
					DEPRESSION	2006-11-09	YES	YES
					HYPERTENSION	2006	YES	YES
					ALZHEIMER	2005	YES	YES
					SINUS BRADYCARDIA	2010-09-06	NO	
					CARDIAL ARRHYTHMIA	2006-10-04	NO	
					DIFFUSE DILATIVE SUPRAAORTIC SCLEROSIS	2006-10-04	YES	NO

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
Placebo	049	21	-51	06SEP2010	OCCLUSION OF VERTEBRAL ARTERY, LEFT WITH COLLATERAL FLOW	2006-10-04	YES	NO
					HIP TEP LEFT	2006-11-16	NO	
					RENAL RETENTION	2009-09-04	NO	
					HYPERTENSIVE CRISIS	2009-09-02	NO	
					BIMALLEOLAR FRACTURE RIGHT	2009-09-28	NO	
					ANKLE OPERATION	2009-08-28	NO	
					SUBSEGMENTAL PULMONARY EMBOLISM, BASAL, RIGHT	2009-09-02	NO	
					RECURRING URINARY TRACT INFECTIONS + POLLAKISURIA	2010-10-13	YES	YES
					AV BLOCK I	2010-09-06	NO	
					ABDOMINAL PAIN	2007	YES	NO
	051	21	-52	06SEP2010	HYPOTHYROIDISM	2008-10-03	YES	YES
					HYPERCHOLESTEROLEMIA	2009	YES	YES
					THYROID SURGERY	2008-09-17	NO	
					FEMORAL NECK FRACTURE	2008	NO	
					STRUMA MULTI NODOSA II WITH MULTIFOCAL AUTONOMY	2008-05-30	NO	
	056	5	-21	31MAR2010	ARTERIAL HYPERTENSION	2005	YES	YES
					FRACTURE LUMBAR VERTEBRA BODY	2009-09	NO	
					OSTEOPOROSIS	2009-09	YES	YES

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
Placebo	056	5	-21	31MAR2010	SPINAL CANAL STENOSIS	2010-03-15	YES	YES
	058	1	-21	06DEC2010	ZENKER DIVERTIKEL SURGERY	2010-11-04	NO	
	059	1	-2	27DEC2010	ARTERIAL HYPERSTENSION	2008	YES	YES
					APPENDECTOMY	1950	NO	
					SHORT PQ-TIME ABNORMAL	2010-12-27	YES	NO
					REPOLARISATION V3-V6 IN ECG			
					INTERMITTANT PAIN OF THE RIGHT	2010-04	YES	YES
					ARCHILLES TENDON AFTER A FALL OF			
					THE BIKE			
	065	16	-20	10AUG2010	ART. HYPERTENSION	2000	YES	YES
					ATRIAL FIBRILLATION	2007	YES	YES
					DIAB. MELLITUS	2000	YES	YES
					HYPERLIPIDEMIA	2005	YES	NO
					ALCOHOL DEPENDENCE	2005	YES	NO
	068	16	-27	26OCT2010	STRUMA	1985	YES	YES
					INTERMITTENT ATRIAL FIBRILATION	2006	YES	NO
					RESTLESS LEGS SYNDROME	2003	YES	NO
					HYPERLIPIDAEMIA	2003	YES	YES
					OPEN-ANGLE-GLAUCOMA	2007-02	YES	YES
					ARTERIAL HYPERTENSION	2003	YES	YES

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Listing 16.2.4.3.1: Medical and surgical history other than AD

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
Placebo	068	16	-27	26OCT2010	CERVICAL SPINE SYNDROME	1988	YES	NO
	069	23	-13	24NOV2010	HYPERTONIE	1990-10-01	YES	YES
					PANKREAS ENZYMDEFEKT	2007-10-01	YES	YES
	072	18	-20	01DEC2010	DIARRHOEA	2009	NO	
					SURGERY LEFT HIP COXARTHROSIS	2009-07-14	NO	
					COXARTHROSIS	2005	YES	YES
					TROCHANDER TENDINOPATHY LEFT LEG	2008-08-15	YES	NO
					HYPERCHOLESTERINAEMIA	2005-09	YES	YES
					ARTERIOSCLEROSIS	2005-08	YES	NO
					HYPERTENSION	2000-11	YES	YES
					BRADYCARDIA	2008-09-17	YES	NO
					VARICOSIS	2008-09-17	YES	NO
					CORONAR HEART DISEASE	2005-09	YES	YES
					TORSIONSSKOLIOSIS LUMBAR	2008-10	YES	NO
					LORDOSIS LUMBAR SACRAL	2008-10	YES	NO
					OBSTIPATION	2008	YES	NO
					CATARACT LEFT	2009	NO	
					CATARACT RIGHT	2010-06-18	YES	NO
					SURGERY RIGHT HIP COXARTHROSIS	2010-05-19	NO	
	079	13	-18	19JUL2010	HYPERTENSION	2005	YES	YES
					POLY-ARTHROSIS	1956	YES	NO

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Treat- ment	Random No.	Site ID	Actual day	Date of visit	Finding	Approx. date of diagnosis [YYYY-MM-DD]	On- go- ing	If ongoing, treatment required?
Placebo	079	13	-18	19JUL2010	PRESBYOPIA	1989	YES	NO
					ABSCCESS CERVICAL	1949	NO	
					WASP-ALLERGY	1949	YES	NO
					CORONARY HEART DISEASE	1996	YES	NO
					HEPATITIS	1950	NO	
					DEPRESSION	2008-05	YES	YES
					BRADYCARDIA	2008	YES	NO
					HYPERCHOLESTERINEMIA	2003	YES	YES
	082	17	-8	06OCT2010	ARTERILLER HYPERTONUS	2002-05	YES	YES
	084	17	-9	08NOV2010	HYPERTENSION	2000-08	YES	YES
					ENDOPROTHESIS ONE KNEE	2009-01	NO	
					FRACTURE THIGH, SHOULDER	2009-12	NO	
					ENDOPROTHESIS ONE KNEE	2009-08	NO	
					HYPERCHOLESTERIN??MIA	2000-08	YES	YES
					CARDIALGIA	2010-05-28	YES	YES
	086	21	-24	04OCT2010	HYPOTHYROIDISM	2003	YES	YES
					DEPRESSION	2003-10-29	YES	YES
					OSTEOPOROSIS	2006-09	YES	YES
					HYPERTENSION	2003	YES	YES
					MILD COGNITIVE IMPAIRMENT	2003-10-29	NO	
					VASCULAR ENCEPHALOPATHY	2003-10-29	YES	NO

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Placebo	086	21	-24	04OCT2010	HIP OPERATION	2006-09-06	NO	
					CHEVRON OSTEOTOMY	2010-02-04	NO	
					VARICOSE VEINS	2006	NO	
					SURGICAL TREATMENT OF VARICOSE VEINS	2006	NO	
					HALLUX VALGUS	2010-01-29	YES	NO
					COXARTHROSIS	2006	NO	
					THYROIDECTOMY	2003	NO	
					CATARACTA CORTICO-NUCLEARIS SENILIS		NO	
	088	16	-9	30NOV2010	HYPOTHYROIDISM	2008	YES	YES
					GYNAECOLOGICAL TOTAL EXSTIRPATION	2007-09	NO	
					INTERVERTEBRAL DISK DEGENERATION OF CERVICAL VERTEBRA (CERVICAL)	2000	YES	NO
					DEPRESSION (MDE)	2003	NO	
					FEAR (MDE)	2003	NO	
					SUICIDAL THOUGHTS (MDE)	2003	NO	
					ALCOHOL CONSUMPTION (MDE)	2003	NO	

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Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	ANEMIA	SLIGHT ANEMIA
	EOSINOPHILIA THROMBOCYTOPENIA	EOSINOPHILIC GRANULOCYTOSIS THROMBOPENIA	EOSINOPHILE GRANULOCYTOPENIA THROMBOPENIE
CARDIAC DISORDERS	ANGINA PECTORIS ARRHYTHMIA ATRIAL FIBRILLATION	CARDIALGIA ARRHYTHMIA CARDIAC (NOS) ATRIAL FIBRILLATION	CARDIALGIA CARDIAL ARRYTHMIA ATRIAL FIBRILLATION INTERMITTENT ATRIAL FIBRILATION
	ATRIOVENTRICULAR BLOCK FIRST DEGREE BRADYCARDIA BUNDLE BRANCH BLOCK LEFT BUNDLE BRANCH BLOCK RIGHT CORONARY ARTERY DISEASE	AV BLOCK FIRST DEGREE BRADYCARDIA LEFT BUNDLE BRANCH BLOCK RIGHT BUNDLE BRANCH BLOCK CORONARY HEART DISEASE	AV BLOCK I BRADYCARDIA LEFT BUNDLE BRANCH BLOCK RIGHT BUNDLE BRANCH BLOCK CORONAR HEART DISEASE CORONARY HEART DISEASE HEART DISEASE
	MYOCARDIAL INFARCTION SINUS BRADYCARDIA	MYOCARDIAL INFARCTION SINUS BRADYCARDIA	MYOCARDIAL INFARCTS SINUS BRADYCARDIA SINUSBRADYCARDIA
	CONGENITAL VISUAL ACUITY REDUCED MIXED HYPERLIPIDAEMIA	CONGENITAL VISUAL ACUITY REDUCED MIXED HYPERLIPIDEMIA	VISUS DEFICIENCY SINCE BIRTH MIXED HYPERLIPIDEMIA
	CONGENITAL, FAMILIAL AND GENETIC DISORDERS		
EAR AND LABYRINTH DISORDERS	DEAFNESS HYPOACUSIS	HEARING LOSS HEARING DECREASED HYPOACUSIS	HEARING LOSS AUDITORY DEFICIENCY HYPACUSIS

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
EAR AND LABYRINTH DISORDERS	PRESBYACUSIS	PRESBYACUSIS	PRESBYAKUSIS
	TINNITUS	TINNITUS	TINNITUS
	VERTIGO	VERTIGO	VERTIGO
ENDOCRINE DISORDERS	GOITRE	GOITRE	GOITER
		NON-TOXIC MULTINODULAR GOITRE	STRUMA
	HYPERALDOSTERONISM	HYPERALDOSTERONISM	STRUMA MULTI NODOSA II WITH MULTIFOCAL AUTONOMY
			HYPERALDOSTEROISM
	HYPOTHYROIDISM	HYPOTHYROIDISM	HYPERTHYREOSIS
			HYPERTHYROIDISM
EYE DISORDERS	CATARACT	CATARACT (LEFT)	THYROID HYPERFUNCTION
			HYPOTHYREOSIS
			HYPOTHYRIOSIS
	CATARACT NUCLEAR	CATARACT (RIGHT)	HYPOTHYROIDISM
			HYPOTHYROIDISM
			THYROID GLAND INSUFFICIENCY
	HYPERMETROPIA	CATARACT BILATERAL NOS	HYPEROPIA
			HYPEROPIA BILATERAL
			HYPEROPIE
	MACULAR DEGENERATION	NUCLEAR CATARACT	DRY AGE-RELATED MACULAR DEGENERATION
			MYOPIA (WEAR GLASSES)
	MYOPIA	MYOPIA	

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
EYE DISORDERS	OPEN ANGLE GLAUCOMA PRESBYOPIA RETINAL VASCULAR THROMBOSIS VISUAL IMPAIRMENT	OPEN ANGLE GLAUCOMA PRESBYOPIA THROMBOSIS EYE VISUAL DISTURBANCE NOS	OPEN-ANGLE-GLAUCOMA PRESBYOPIA THROMBOSIS EYE RIGHT VISUS DEFICIENCY
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN ABDOMINAL PAIN UPPER CONSTIPATION DIARRHOEA DIVERTICULUM DYSPEPSIA FAECAL INCONTINENCE GASTRITIS ATROPHIC HIATUS HERNIA INGUINAL HERNIA NAUSEA PANCREATIC INSUFFICIENCY REFLUX OESOPHAGITIS	ABDOMINAL PAIN STOMACH PAIN CONSTIPATION DIARRHOEA DIVERTICULOSIS PYROSIS INCONTINENCE FECAL ATROPHIC GASTRITIS HIATUS HERNIA INGUINAL HERNIA NAUSEA PANCREATIC INSUFFICIENCY REFLUX OESOPHAGITIS	ABDOMINAL PAIN RECURRENT STOMACHE PAIN OBSTIPATION DIARRHOEA DIVERTICULOSIS PYROSIS INCONTINENCE OF FECAL ATROPHIC GASTRITIS, HELIOBACTER PYLORI SMALL AXIAL HIATUS HERNIA INGUINAL HERNIATION NAUSEA PANKREAS ENZYMDEFEKT REFLUX ESOPHAGITIS I REFLUXOESOPHAGITIS
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	FEELING COLD	FEELING OF COLDNESS
HEPATOBIILIARY DISORDERS	HEPATIC STEATOSIS HEPATITIS	HEPATIC STEATOSIS HEPATITIS	STEATOSIS HEPATIS I HEPATITIS

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
IMMUNE SYSTEM DISORDERS	ALLERGY TO ARTHROPOD STING	ALLERGIC REACTION TO WASP STING	WASP-ALLERGY
	SARCOIDOSIS	SARCOIDOSIS	SARCOIDOSIS
INFECTIONS AND INFESTATIONS	ABSCESS NECK	CERVICAL ABSCESS	ABSCESS CERVICAL
	BORRELIA INFECTION	BORRELIA INFECTION	BORRELIA INFECTION
	CHLAMYDIAL INFECTION	CHLAMYDIAL INFECTION	POSITIVE LABORATORY RESULT OF CHLAMYDIA
	HEPATITIS B	HEPATITIS B	HEPATITIS B INFECTION
	HERPES ZOSTER	HERPES ZOSTER	ZOSTER
	LYME DISEASE	BORRELIA BURGDORFERI INFECTION	POSITIVE LABORATORY RESULT OF BORRELIA BURGDORFERI
	ONYCHOMYCOSIS	ONYCHOMYCOSIS	ONYCHOMYCOSIS BOTH FEET
	PERTUSSIS	PERTUSSIS	PERTUSSIS
	TUBERCULOSIS	INFECTION TBC	TBC-INFECTION
	URINARY TRACT INFECTION	URINARY TRACT INFECTION	RECURRING URINARY TRACT INFECTIONS + POLLAKISURIA
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANKLE FRACTURE	BIMALLEOLAR FRACTURE	BIMALLEOLAR FRACTURE RIGHT
	CLAVICLE FRACTURE	CLAVICLE FRACTURE	FRACTURE OF RIGHT CLAVICLE
	CONCUSSION	COMMOTIO CEREBRI	COMMOTIO CEREBRI I (FIRST DEGREE)
	FEMORAL NECK FRACTURE	FEMORAL NECK FRACTURE	FEMORAL NECK FRACTURE
	FRACTURE	FRACTURE BONE	FRACTURE THIGH, SHOULDER
	HEAD INJURY	HEAD INJURY	HEAD INJURY
	LUMBAR VERTEBRAL FRACTURE	LUMBAR VERTEBRAL FRACTURE	HEAD TRAUMA (AT AGE 18) FRACTURE LUMBAR VERTEBRA BODY

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRAUMATIC HAEMATOMA	TRAUMATIC HEMATOMA	APOPLEXY OF THE RIGHT INDEX FINGER
INVESTIGATIONS	ARTHROSCOPY	ARTHROSCOPY	ARTHROSCOPIA
	BLOOD CREATININE INCREASED	CREATININE INCREASED	ELEVATED CREATININE
	BLOOD THYROID STIMULATING HORMONE DECREASED	TSH DECREASED	SLIGHT ABNORMAL TSH VALUE
	BLOOD UREA INCREASED	INCREASED UREA	ELEVATED UREA
	ELECTROCARDIOGRAM QT PROLONGED	ELECTROCARDIOGRAM QTC INTERVAL PROLONGED	PROLONGATED QTC TIMES
	ELECTROCARDIOGRAM REPOLARISATION ABNORMALITY	ELECTROCARDIOGRAM REPOLARISATION ABNORMALITY	SHORT PQ-TIME ABNORMAL REPOLARISATION V3-V6 IN ECG
	ELECTROCARDIOGRAM T WAVE INVERSION	NEGATIVE T WAVE	ECG-ABNORMALITIES (T-NEGATIVATION ON V2) NON CORONARY NEGATIVE TIN LEAD 3
	WHITE BLOOD CELL COUNT INCREASED	LEUKOCYTE COUNT INCREASED	ELEVATED LEUKOCYTES
METABOLISM AND NUTRITION DISORDERS	DIABETES MELLITUS	DIABETES MELLITUS	DIAB. MELL.
	DYSLIPIDAEMIA	DYSLIPOPROTEINEMIA	DIAB. MELLITUS
	FOLATE DEFICIENCY	FOLIC ACID DEFICIENCY	DIABETES MELLITUS
	HYPERCHOLESTEROLAEMIA	HYPERCHOLESTEROLEMIA	DYSLIPOPROTEINEMIA
			FOLIC ACID DEFICIENCY
			HYPERCHOLESTERIN?MIA
			HYPERCHOLESTERINAEMIA
			HYPERCHOLESTERINAMIA
			HYPERCHOLESTERINEMA

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	HYPERCHOLESTEROLEMIA	HYPERCHOLESTERINEMIA
			HYPERCHOLESTEROLAEMIA
	HYPERHOMOCYSTEINAEMIA	HYPERHOMOCYSTEINEMIA	HYPERCHOLESTEROLEMIA
			HYPERHOMOCYSTEINEMIA
	HYPERLIPIDAEMIA	HYPERLIPIDEMIA	HYPERHOMOZYTEINEMIA
			HYPERLIPIDAEMIA
	HYPERURICAEMIA	HYPERURICEMIA	HYPERLIPIDEMIA
			HYPERURICAEMIA
	HYPOVITAMINOSIS	HYPOVITAMINOSIS	HYPERURICEMIA
		VITAMIN DEFICIENCY	HYPERURIKEMIA
			HYPOVITAMINOSIS
			B12-HYPOVITAMINOSE
			(SUBSTITUTION)
	TYPE 1 DIABETES MELLITUS	DIABETES MELLITUS	INSULINDEPENDENT DIABETES
		INSULIN-DEPENDENT	MELLITUS
	TYPE 2 DIABETES MELLITUS	TYPE I DIABETES MELLITUS	DIABETES TYPE I
VITAMIN B COMPLEX DEFICIENCY		TYPE II DIABETES MELLITUS	DIABETES MELLITUS TYP II
		UNSPECIFIED VITAMIN B	VITAMIN B12 DEFICIENCY
		DEFICIENCY	
VITAMIN B12 DEFICIENCY		VITAMIN B12 DEFICIENCY	B12 - DEFICIENCY
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	KNEE PAIN	KNEE PAIN
	FOOT DEFORMITY	HALLUX VALGUS	HALLUX VALGUS
	INTERVERTEBRAL DISC DEGENERATION	CERVICAL DISC DEGENERATION	INTERVERTEBRAL DISK DEGENERATION OF CERVICAL VERTEBRA (CERVICAL)

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	INTERVERTEBRAL DISC HERNIATION	HERNIATED VERTEBRAL DISC
		PROLAPSED CERVICAL DISC	DISCUSPROLAPS C5/6
		PROLAPSED LUMBAR DISC	DISCUSPROLAPS S4/5
	LORDOSIS	LORDOSIS	LORDOSIS LUMBAR SACRAL
	MUSCLE SPASMS	CRAMPS CALF	CRAMPS IN THE CALF
		LEG CRAMPS	MUSCLE CRAMPS OF THE LEGS
	MUSCULOSKELETAL PAIN	SHOULDER PAIN	PAIN IN RIGHT SHOULDER AFTER FALL
	OSTEOARTHRITIS	ARTHROSIS	ARTHROSIS OF FINGER JOINTS
		COXARTHROSIS	COXARTHROSIS
			SURGERY LEFT HIP COXARTHROSIS
			SURGERY RIGHT HIP COXARTHROSIS
		GONARTHROSIS	ARTHROSIS OF RIGHT KNEE
			KNEE ARTHROSIS
	OSTEOPOROSIS	OSTEOPOROSIS	OSTEOPOROSIS
	POLYARTHRITIS	POLYARTHRITIS	POLY-ARTHROSIS
	SCOLIOSIS	SCOLIOSIS	LWS-SKOLIOSIS RIGHT KONVEX SCOLIOSIS
			TORSIONSSKOLIOSIS LUMBAR
	SPINAL COLUMN STENOSIS	SPINAL STENOSIS NOS	SPINAL CANAL STENOSIS
	SPINAL OSTEOARTHRITIS	SPONDYLOSIS	SPONDYLOSIS HYPERASTETICA THORACOLUMBAL
	SPONDYLOLISTHESIS	SPONDYLOLISTHESIS	SPONDYLOLISTHESIS L5/51
	TENDON DISORDER	TENDINOSIS	TROCHANDER TENDINOPATHY LEFT LEG
	TENDON PAIN	ACHILLES TENDON PAIN	INTERMITTANT PAIN OF THE RIGHT ARCHILLES TENDON AFTER A FALL OF THE BIKE

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	BREAST CANCER	BREAST CARCINOMA	MAMMA CARCINOMA RIGHT WITH RESECTION AND RADIOTHERAPY
	MENINGIOMA	MENINGIOMA	CALCIFIED MENINGIOMA
	PROSTATIC ADENOMA	PROSTATIC ADENOMA	ADENOMA OF PROSTATA (ENUKLATION)
	UTERINE LEIOMYOMA	UTERINE MYOMA	MYOMA MYOPIA
NERVOUS SYSTEM DISORDERS	CARPAL TUNNEL SYNDROME	CARPAL TUNNEL SYNDROME	CARPALTUNNELSYNDROME
	CEREBRAL ISCHAEMIA	CEREBRAL ISCHAEMIA	CARPALTUNNELSYNDROME RIGHT
	CERVICOBRACHIAL SYNDROME	CERVICAL SYNDROME	CEREBRAL ISCHAEMIA
	COGNITIVE DISORDER	COGNITIVE IMPAIRMENT	CERVICAL SPINE SYNDROME
	DEMENTIA ALZHEIMER'S TYPE	ALZHEIMER'S DISEASE	MILD COGNITIVE IMPAIRMENT
			AD
			ALZHEIMER
	HEADACHE	HEADACHE RECURRENT	ALZHEIMER'S DISEASE
			RECURENT HEADACHE
			RECURRING HEAD ACHE
	MIGRAINE	MIGRAINE	MIGRAINE
	POLYNEUROPATHY	POLYNEUROPATHY	POLYNEUROPATHY DISTAL
	RESTLESS LEGS SYNDROME	SYNDROME RESTLESS LEGS	RESTLESS LEGS SYNDROME
	SCIATICA	LUMBOISCHIALGIA	LUMBO ISCHIALGIA RIGHT
	SYNCOPE	SYNCOPE	SYNCOPE
	VASCULAR ENCEPHALOPATHY	SUBCORTICAL VASCULAR ENCEPHALOPATHY	SUBCORTICAL ENCEPHALOPATHY
		VASCULAR ENCEPHALOPATHY	VASCULAR ENCEPHALOPATHY

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
NERVOUS SYSTEM DISORDERS	VERTEBRAL ARTERY OCCLUSION	VERTEBRAL ARTERY OCCLUSION	OCCLUSION OF VERTEBRAL ARTERY, LEFT WITH COLLATERAL FLOW
PSYCHIATRIC DISORDERS	ABNORMAL BEHAVIOUR	BEHAVIOUR DISORDER	BEHAVIOURAL DISEASE, AGGRESSIVENESS DISTURBANCE
	AFFECTIVE DISORDER	MOOD DISORDER NOS	MOOD DISORDER (DEPRESSEION)
	AGGRESSION	AGGRESSIVE BEHAVIOUR	MILD AGGRESSIV BEHAVIOR
	ALCOHOLISM	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE	ALCOHOL DEPENDENCE
	ANXIETY	ANXIETY REACTION	REACTION OF ANXIETY
	DEPRESSION	DEPRESSION	DEPRESSION
			DEPRESSION (MDE)
			MILD TO MODERATE DEPRESSION
		DEPRESSIVE DISORDER	DEPRESSIVE DISORDER
	FEAR	FEAR	FEAR (MDE)
	HYPOCHONDRIASIS	HYPOCHONDRIASIS	HYPOCHONDRIA
	INSOMNIA	INSOMNIA	INSOMNIA
	SUICIDAL IDEATION	SUICIDAL IDEATION	SUICIDAL THOUGHTS (MDE)
RENAL AND URINARY DISORDERS	INCONTINENCE	INCONTINENCE	INCONTINENCE
	PROTEINURIA	PROTEINURIA	ELEVATED PROTEINE (URINE)
	URINARY INCONTINENCE	INCONTINENCE OF URINE	INCONTINENCE OF URINE
	URINARY RETENTION	URINARY RETENTION	RENAL RETENTION
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	BENIGN PROSTATIC HYPERPLASIA	PROSTATIC HYPERPLASIA	HYPERPLASIA OF PROSTATE
		PROSTATIC HYPERTROPHY	PROSTATAHYPERTROPHY
	MENOPAUSAL SYMPTOMS	MENOPAUSAL HOT FLUSHES	HOT FLASH SINCE MENOPAUSE

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	MENOPAUSAL SYMPTOMS	POSTMENOPAUSAL SYMPTOMS	POSTMENOPAUSAL DISCOMFORT
	PROSTATIC HYPOPLASIA	PROSTATIC HYPOPLASIA	PROSTATAHYPOPLASIEA
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASTHMA	ASTHMA BRONCHIAL	ASTHMA BRONCHIALE
	PULMONARY EMBOLISM	PULMONARY EMBOLISM	SUBSEGMENTAL PULMONARY EMBOLISM, BASAL, RIGHT
	PULMONARY SARCOIDOSIS SLEEP APNOEA SYNDROME	PULMONARY SARCOIDOSIS SLEEP APNOEA SYNDROME	PILMONARY SARCOIDOSIS SLEEP APNOE SYNDROM
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS ALLERGIC	ALLERGIC EXANTHEMA	MILD LOCAL EXANTHEMA CAUSED BY RIVASTIGMIN TAPE
	HYPERHIDROSIS	SWEATING INCREASED	INCREASE SWEATING, ORIGIN UNKNOWN
	PSORIASIS	PSORIASIS	PSORIASIS
SOCIAL CIRCUMSTANCES	ALCOHOL USE	ALCOHOL USE	ALCOHOL CONSUMPTION (MDE)
SURGICAL AND MEDICAL PROCEDURES	ANKLE OPERATION	ANKLE OPERATION	ANKLE OPERATION
	APPENDICECTOMY	APPENDECTOMY	ANKLE OPERATION AFTER TRAUMA ABLATION OF APPENDIX APPENDECTOMY
	CAESAREAN SECTION	CAESAREAN SECTION CESAREAN SECTION	DELIVERY BY CAESARIAN SECTION SECTIO
	CARPAL TUNNEL DECOMPRESSION	CARPAL TUNNEL DECOMPRESSION	CARPAL-TUNNEL-SYNDROM - SUGERY (RIGHT HAND) OP CARPAL TUNNEL SYNDROME

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
SURGICAL AND MEDICAL PROCEDURES	CATARACT OPERATION	CATARACT OPERATION	CATARACT SURGERY
	CHOLECYSTECTOMY	CHOLECYSTECTOMY	CATARACT SURGERY BOTH SIDES
	CHOLELITHOTOMY	CHOLELITHOTOMY	CHOLECYSTECTOMY
	CORONARY ARTERIAL STENT INSERTION	CORONARY STENT PLACEMENT	CHOLELITHIASIS SURGERY
			CORONARY HEART DISEASE WITH STENT (RIVA-PCTA)
			CORONARY HEART DISEASE, STENT-IMPLANTATION
	GASTRECTOMY	GASTRECTOMY PARTIAL	STENT IMPLANTATION
	HIP ARTHROPLASTY	HIP REPLACEMENT	SECTION OF A PART OF GASTRIC DUE TO ULCERA
	HIP SURGERY	HIP OPERATION NOS	HIP TEP LEFT
	HYSTERECTOMY	HYSTERECTOMY	HIP OPERATION
			HYSTERECTOMY
			HYSTERECTOMY DUE TO UTERINE PROLAPSE
	HYSTEROSALPINGO-OOPHORECTOMY	TOTAL HYSTERECTOMY OVARIOHYSTERECTOMY	TOTAL HYSTERECTOMY
	INTERVERTEBRAL DISC OPERATION	PROLAPSED DISC REPAIR	GYNAECOLOGICAL TOTAL EXSTIRPATION
	KNEE ARTHROPLASTY	KNEE PROSTHESIS INSERTION	LUMBAR DISCUS PROLAPS SURGERY
	KNEE OPERATION	KNEE OPERATION	ENDOPROTHESIS ONE KNEE
	MASTECTOMY	MASTECTOMY	KNEE ENDOPROTHESIS LEFT LEG
			KNEE JOINT SURGERY
			N. MAMMAE RIGHT, ST.P.
			MASTECTOMIA
	MENISCUS OPERATION	MENISCUS OPERATION	KNEE ARTHROSCOPY (MENISCOPATHIE)

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
SURGICAL AND MEDICAL PROCEDURES	NEPHRECTOMY	NEPHRECTOMY	KIDNEY EXCISION AFTER KIDNEY-TBC
	OSTEOTOMY	OSTEOTOMY	CHEVRON OSTEOTOMY
	PHARYNGEAL OPERATION	ZENKER'S DIVERTICULOTOMY	ZENKER DIVERTIKEL SURGERY
	PROSTATIC OPERATION	PROSTATIC OPERATION	PROSTATA HYPERPLASIA SURGERY
			PROSTATE SURGERY
	SHOULDER OPERATION	SHOULDER OPERATION	SHOULDER JOINT SURGERY
			SHOULDER OPERATION AFTER TRAUMA
	SPINAL FUSION SURGERY	FUSION OF VERTEBRA	FUSION LWK 5/6 FOR CHRONICAL BACK PAIN
	THYROID OPERATION	THYROID OPERATION	THYROID SURGERY
	THYROIDECTOMY	STRUMECTOMY	STRUMECTOMY
		THYROIDECTOMY	THYROID RESECTION
			THYROIDECTOMY
			THYROIDECTOMY BECAUSE OF THYROID CARCINOMA
	TONSILLECTOMY	TONSILLECTOMY	TONSELLEKTOMIA
			TONSILLECTOMY
	TRANSURETHRAL PROSTATECTOMY	PROSTATE TRANSURETHRAL RESECTION	TRANSURETHRAL RESECTION OF PROSTATIC GLAND
	TUMOUR EXCISION	FIBROADENOMA REMOVAL	MAMMA ADENOMA RESECTION
	VARICOSE VEIN OPERATION	VARICOSE VEIN OPERATION	VARICOSIS SURGERY
		VARICOSE VEINS STRIPPING	SURGICAL TREATMENT OF VARICOSE VEINS
VASCULAR DISORDERS	AORTIC ARTERIOSCLEROSIS	AORTIC SCLEROSIS	DIFFUSE DILATIVE SUPRAAORTIC SCLEROSIS
	ARTERIOSCLEROSIS	ARTERIOSCLEROSIS	ARTERIOSCLEROSIS

Listing 16.2.4.3.2: MedDRA (Version 12.1) diseases and associated Investigators Term

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System Organ Class Term	Preferred Term	Lower Level Term	Investigators Term
VASCULAR DISORDERS	ESSENTIAL HYPERTENSION HYPERTENSION	ESSENTIAL HYPERTENSION BLOOD PRESSURE HIGH HYPERTENSION HYPERTENSION ARTERIAL	ESSENTIELLE HYPERTENSION HIGH BLOOD PRESSURE HYPERTENSION HYPERTONIA HYPERTONIE HYPERTONUS ART. HYPERTENSION ART. HYPERTONUS ARTERIAL HYPERSTENSION ARTERIAL HYPERTENSION ARTERIAL HYPERTONUS ARTERILLER HYPERTONUS HYPERTENSIVE CRISIS
	HYPERTENSIVE CRISIS MICROANGIOPATHY TEMPORAL ARTERITIS VARICOSE VEIN	HYPERTENSIVE CRISIS MICROANGIOPATHY TEMPORAL ARTERITIS VARICOSE VEINS VARICOSE VEINS NOS	MILD CEREBRAL MICROANGYOPATHY TEMPORAL ASTERITIS VARICOSIS VARICOSE VEINS

Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
ACI-91	002	1	DONEPEZIL	2008-12-15		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			CITALOPRAM	2008-12-15		YES	PO	0020	MG	OAD	DEPRSSION
			INTRAUTERIN PESSAR	2004		YES					CONTRACEPTION
			IBUPROFEN	2009-04-24	2009-04-24		PO	0400	MG	OAD	HEADACHE
			IBUPROFEN	2009-04-27	2009-04-27		PO	0900	MG	OAD	HEADACHE
	004	1	ALLOPURINOL	1987		YES	PO	0100	MG	OAD	HYPERURICAEMIA
			RIVASTIGMIN	2008-03-31		YES	ID-TRANSD	0009.5	MG	OAD	ALZHEIMER DISEASE
	006	2	NILVADIPIIN	2008	2010-01-25		PO	UNK	UNK	OAD	HYPERTENSION
			CANDESARTAN	2010-01-25		YES	PO	16	MG	OAD	HYPERTENSION
			HCT	2010-01-25		YES	PO	0012.5	MG	OAD	HYPERTENSION
			DONEZEPIL	2009-09-15		YES	PO	0010	MG	OAD	ALZHEIMER`S DISEASE
			ASS	2010-11-10	2010-11-10		PO	0500	MG	OAD	HEADACHE
	010	1	BISOPROLOL	2009-05-29		YES	PO	0001.25	MG	OAD	HIGH BLOOD PRESSURE
			DONEPEZIL	2006-08-29		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			VENLAFAXIN	2009-05-05		YES	PO	0225	MG	OAD	DEPRESSION
			RAMIPRIL	2009-05-29		YES	PO	0005	MG	BID	HIGH BLOOD PRESSURE
			NIFEDIPIN	2009-05-07	2009-05-07		PO	0005	MG	OAD	HYPERTENSIVE CRISIS
			DICLOFENAC	2009-10-21	2009-11-20		PO	0075	MG	OAD	PAIN IN LEFT KNEE

NK/UNK/UKN=not known, OAD=once a day, AR=as required, BID=twice a day, TID=three times a day

PO=oral, TP=topical, IV=intravenous, ID=intradermal, IM=intramuscular, SC=subcutaneous

MCG=microgram, ML=milliliter, CAP=capsules, MG=milligram, TBL=tablets, IU=International Units, G=gram, U=units, GTT=drops
1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
ACI-91	010	1	OMEPRAZOL	2009-10-21	2009-11-20		PO	0040	MG	OAD	GASTRIC PROTECTION
			ENOXAPARIN-NATRIUM	2009-11-12	2009-11-20		SC	7000	I.E.	BID	LEG THROMBOSIS
			PHENPROCUMON	2009-11-12		YES	PO		MG	OAD	LEG THROMBOSIS
			QUETIAPIN	2009-11-04		YES	PO	0025	MG	OAD	DELUSIONAL SYMPTOMS
	012	1	DONEPEZIL	2010-02-04		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			IBUPROFEN	2010-09-10		YES	PO	0600	MG	BID	LUMBOISCHIALGIA
			DICLOFENAC	2010-10-19	2010-10-19		IM	0075	MG	OAD	LUMBOISCHIALGIA
	014	4	DONEPEZIL	2007-02		YES	PO	0010	MG	OAD	ALZHEIMER\
			VITAMIN B12	2009-06-03	2009-09-14		IM	0100	MCG	OAM	B12 HYPOVITAMINOSIS
			DICLOFENAC	2009-11-02	2009-11-02		PO	0075	MG	OAD	HEADACHE AFTER CFS PUNCTURE
	015	4	DONEPEZIL	2004-01		YES	PO	10	MG	OAD	ALZHEIMER`S DISEASE
			RAMIPRIL	2008-12	2010-05-14		PO	0002.5	MG	OAD	ART. HYPERTENSION
			SIMVASTATIN	2005-08		YES	PO	20	MG	OAD	HYPERCHOLESTERINEMIA
			PANTOZOL	2008-12		YES	PO	20	MG	OAD	PYROSIS
			OESTROGENE +	2004	2009-12		PO	0000.3	MG	OAD	POSTMENOPAUSAL
			MEDROGESTON (PRESOMEN)								SYMPTOMS

NK/UNK/UKN=not known, OAD=once a day, AR=as required, BID=twice a day, TID=three times a day

PO=oral, TP=topical, IV=intravenous, ID=intradermal, IM=intramuscular, SC=subcutaneous

MCG=microgram, ML=milliliter, CAP=capsules, MG=milligram, TBL=tablets, IU=International Units, G=gram, U=units, GTT=drops

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum

16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
ACI-91	015	4	CANDESARTAN	2010-05-20	2010-07		PO	0004	MG	OAD	ART. HYPERTENSION
			CANDESARTAN	2010-07		YES	PO	8	MG	OAD	ART. HYPERTENSION
	017	5	CIPRAMIL	2008-10-02		YES	PO	0020	MG	OAD	DEPRESSIVE SYMPTOMS
			ALLOPURINOL	1966-01-01		YES	PO	0300	MG	OAD	HYPERURICAEMIA
			TRIAMTEREN	2007-05-01		YES	PO	0050	MG	OAD	HYPERTENSION
			ARICEPT	2008-05-01		YES	PO	0010	MG	OAD	DEMENTIA
			SIMVASTATIN	2009-04-24		YES	PO	0030	MG	OAD	HYPERCHOLESTERINAEMIA
			TRIAMCINOLON	2009-11-16	2009-11-25		TP	0010	MG	OAD	FUNGAL SKIN INFECTION
			ACETONID								
			CLOTRIMAZOL	2009-11-16	2009-11-25		TP	200	MG	OAD	FUNGAL SKIN INFECTION
			OLEUM ARACHIDIS	2009-11-16	2009-11-25		TP	0002	G	BID	FUNGAL SKIN INFECTION
			UNGUETUM EMULSIS	2009-11-16	2009-11-25		TP	0020	G	BID	FUNGAL SKIN INFECTION
			AQUASUMAC								
			IBUPROFEN	2009-09-23	2009-09-26		PO	0400	MG	BID	PAIN IN SHOULDER
			VACCINATION	2009-09-14	2009-09-14		IM	UNK	ML	OAD	VACCINATION
			INFLUENZA								
			IBUPROFEN	2010-07-26	2010-07-26		PO	0400	MG	BID	PAIN IN SHOULDER
			DEXA-CT	2010-07-27	2010-07-29		IM	0008	MG	OAD	PAIN IN SHOULDER

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
ACI-91	019	5	ASS 100	2003		YES	PO	0100	MG	OAD	CORONARY HEART DISEASE
			METOPROLOLSUCCINAT	2001		YES	PO	95	MG	OAD	HYPERTENSION
			SIMVASTATIN	2001		YES	PO	20	MG	OAD	HYPERCHOLESTERINEMIA
			TAMSULOSINHYDROCHLOR ID	2004		YES	PO	400	MCG	OAD	BPH
			VALSARTAN	2001		YES	PO	80	MG	OAD	HYPERTENSION
			HYDROCHLOROTHIAZID	2001		YES	PO	0012.5	MG	OAD	HYPERTENSION
			DONEPEZIL	2009-06		YES	PO	10	MG	OAD	DEMENTIA
			ALLOPURINOL	1999		YES	PO	100	MG	OAD	HYPERURICAEMIA
			BUPROPION	2010-07-02	2010-07-09		PO	0150	MG	OAD	APATHY
			BUPROPION	2010-07-10	2010-07-16		PO	0300	MG	OAD	APATHY
			BUPROPION	2010-07-17	2010-07-25		PO	0150	MG	OAD	APATHY
	023	4	RIVASTIGMIN (EXELON)	2009-09		YES	TP	0009.5	MG	OAD	ALZHEIMER`S DISEASE
			ECONAZOL	2010-08-17	2010-09-10		TP	1	%	OAD	TINEA PEDIS
			(EPI-PEVARY) CREME								
			ALUMINA GLOBULI	2010-09-08		YES	PO	3	CAP	OAD	DISCOMFORT, MALAISE
			ECONAZOL	2010-11-03		YES	TP	01	%	OAD	TINEA PEDIS
			(EPI-PEVARYL CREME)								
			SINUPRET FORTE	2010-12-09	2010-12-10		PO	1	TBL	TID	SINUSITIS

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Listing 16.2.4.4.1: Previous and concomitant medications

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ACI-91	023	4	OXYBUTYNIN (KENTERA)	2011-01-07		YES	TP	0003.9	MG	AR	FREQUENT MICTURITION
			CIPROFLOX	2011-01-26	2011-01-29		PO	500	MG	BID	MILD BLADDER INFECTION
			TERBINAFIN (DERMATIN)	2011-05-26		YES	PO	250	MG	OAD	TINEA PEDIS
			(BETRAFEN GEL)	2011-05-26		YES	TP	UNK	UNK	BID	TINEA PEDIS
			CICLOPIROX SCHWEDENBITTER (=SWEDISH BITTERS)	2011-07-10		YES	PO	UNK	UNK	AR	FEELING OF COLD
	027	20	EXELON	2010-03-05	2010-04-05		TP	0004.6	MG	OAD	DEMENTIA AD
			EXELON	2010-04-06		YES	TP	0009.5	MG	OAD	DEMENTIA AD
			EFFECTIN	2010-04-15		YES	PO	150	MG	OAD	DEMENTIA ASSOCIATED DEPRESSION
			SIMVASTATIN	2011-01-25		YES	PO	20	MG	OAD	HYPERLIPIDAEMIA
			TAVANIC	2011-07-22	2011-08-01		PO	1000	MG	OAD	PNEUMONIA
			TELFEST	2011-07-22	2011-07-25		PO	120	MG	OAD	ATOPIC DERMATITIS
			ADVANTAN CREME	2011-07-22		YES	TP			OAD	ATOPIC DERMATITIS
			AUGMENTIN	2011-04-13	2011-04-22		PO	1000	MG	OAD	URINARY TRACT INFECTION

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Listing 16.2.4.4.1: Previous and concomitant medications

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ACI-91	030	8	EUTHYROX	1990		YES	PO	100	MCG	OAD	THYROID HYPERFUNCTION
			ARICEPT	2008	2010-03		PO	5	MG	OAD	PROPHYLAXIS
											ALZHEIMER DISEASE
			ARICEPT	2010-03		YES	PO	10	MG	OAD	ALZHEIMER DISEASE
			ACTONEL	2008		YES	PO	35	MG	AR	OSTEOPOROSIS
			BETAHISTIN AL	2007		YES	PO	12	MG	BID	VERTIGO
			ASS 100	2010-03	2010-11-24		PO	100	MG	OAD	MICROANGIOPATHY
			IBUPROFEN	2008		YES	PO	400	MG	AR	OSTEOPOROSIS
			DEKRISTOL	2009		YES	PO	400	IU	QM	OSTEOPOROSIS
			VOMEX A	2010-06-04	2010-06-06		PO	050	MG	OAD	PROPHYLAXIS
			COTRIM FORTE	2010-06-22	2010-06-24		PO	0960	MG	BID	URINARY TRACT INFECTION
			COTRIM FORTE	2010-06-25	2010-08-28		PO	960	MG	OAD	URINARY TRACT INFECTION
			PANTOZOL	2011-03-28		YES	PO	20	MG	OAD	GASTRIC CONSERVATION
	032	8	GALAFEM	2010-04		YES	PO	6500	MCG	OAD	HOT FLASH
			ARICEPT	2008		YES	PO	6	MG	OAD	AD
			BALDRIAN	2010		YES	PO	1	TBL	AR	INSOMNIA
			OMERPAZOL	2008		YES	PO	40	MG	AR	GASTRIC CONSERVATION
			OXAZEPAM	2010-08		YES	PO	10	MG	OAD	INSOMNIA

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Listing 16.2.4.4.1: Previous and concomitant medications

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ACI-91	033	9	OLMETEC PLUS	2007		YES	PO	20	MG	OAD	HYPERTENSION
			CITALOPRAM	2007	2010-07-30		PO	20	MG	OAD	DEPRESSION
			L-THYROXIN	2009-04		YES	PO	75	MCG	OAD	HYPOTHYROIDISM
			ARICEPT	2007-08		YES	PO	0010	MG	OAD	AD
	042	12	CITALOPRAM	2008-12		YES	PO	0020	MG	OAD	LOSS OF INTRA-INDIVIDUAL ACTIVITY
			RAMIPRIL	2008-12		YES	PO	2500	MCG	OAD	ARTERIAL HYPERTONIA
			GALANTAMIN	2009-04		YES	PO	0016	MG	OAD	ALZHEIMER
			SIMVASTATIN	2008-12		YES	PO	0040	MG	OAD	HYPERCHOLESTERINEMIA
			GALANTAMIN	2008-12	2009-04		PO	0008	MG	OAD	AD
			PROMETHAZIN	2008	2010-08-22		PO	0025	MG	AR	EXITATION
			PROMETHAZIN	2010-08-23		YES	PO	0025	MG	OAD	NOCTURNAL EXCITATION
	043	12	METFORMIN	2006		YES	PO	0500	MG	BID	DIABETES
			LERCANIDIPINHYDROCHL	1991	2010-05		PO	0010	MG	OAD	HYPERTONUS
			ORID								
			ASS	2008		YES	PO	0100	MG	OAD	CARDIAC PROPHYLAXIS
			RAMIPRIL	1991	2010-05		PO	0005	MG	OAD	HYPERTONUS
			ARICEPT	2009-01		YES	PO	0010	MG	OAD	AD

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Listing 16.2.4.4.1: Previous and concomitant medications

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ACI-91	043	12	RISPERIDON	2010-01-05	2010-01-18		PO	0500	MCG	BID	HALLUCINATIONS
			EUNERPAN	2010-01-05	2010-01-20		PO	0025	MG	OAD	NOCTURNAL EXCITATION
			ZYPREXA	2010-01-18	2010-01-19		PO	0005	MG	OAD	HALLUCINATIONS
			ZYPREXA	2010-01-20		YES	PO	0010	MG	OAD	HALLUCINATIONS
			EUNERPAN	2010-01-21	2010-05		PO	0050	MG	OAD	NOCTURNAL EXCITATION
			ARICEPT	2008-12	2009-01		PO	0005	MG	OAD	ALZHEIMER
			EUNERPAN	2010-05		YES	PO	0025	MG	OAD	NOCTURNAL EXCITATION
			MOVICOL MACROGOL 3350	2010-05		YES	PO	0013	G	OAD	OBSTIPATION
			BETAMETHASONDIPROPRI ONAT (LOTRICOMB)	2010-01-28	2010-05-15		TP	0640	MCG	BID	INGUINAL INTERTRIGO
			CLOTRIMAZOL (LOTRICOMB)	2010-01-28	2010-05-15		TP	010	MG	BID	INGUINAL INTERTRIGO
			PARACETAMOL	2010-07	2010		PO	0500	MG	TID	FEVER ANALGESIA
			NOVAMINSULFON	2010-07	2010		PO	0500	MG	QID	FEVER ANALGESIA
	046	11	QUETIAPIN	2008		YES	PO	25	MG	OAD	MOOD
			DULOXETIN	2008		YES	PO	60	MG	OAD	MOOD
			ETORICOXIB	2009-04		YES	PO	90	MG	OAD	PAIN
			OMEPRAZOL	2009-04		YES	PO	20	MG	OAD	GASTRIC ACID PROTECTION

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Listing 16.2.4.4.1: Previous and concomitant medications

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13FEB2013

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ACI-91	046	11	METAMIZOL	2009-01	2010-01-25		PO	500	MG	OAD	PAIN
			METAMIZOL	2009-01	2010-01-25		PO	1000	MG	OAD	PAIN
			RIVASTIGMIN	2008-08		YES	ID	0009.5	MG	OAD	DEMENTIA
			MATAMIZOL	2010-01-25		YES	PO	500	MG	BID	PAIN
			PIPAMPERON	2010-11-02		YES	PO	60	MG	BID	UNREST
	048	11	GALANTAMINE	2008-12		YES	PO	16	MG	OAD	DEMENTIA
			FINASTERID	2008		YES	PO	5	MG	OAD	PROSTATEHYPOPLASIA
			ASS	2006		YES	PO	100	MG	OAD	PROPHYLAXIS
			PRAVASTATIN	2009-10		YES	PO	20	MG	OAD	HYPERCHOLESTERIN
	050	21	ADJUVIN, SERTRALIN	2009-10-28	2011-04-10		PO	50	MG	BID	DEPRESSION
			THROMBO ASS	2009		YES	PO	100	MG	OAD	CARDIOVASCULAR PREVENTION
			CEREBOKAN	2009	2010-09-15		PO	80	MG	BID	AD
			TRITTICO	2009-10-28	2011-07-04		PO	50	MG	OAD	DEPRESSION
			REMINYL RETARD	2009-05	2011-04-10		PO	0008	MG	OAD	AD
			TRICEF (CEFIXIM)	2011-06-10	2011-06-16		PO	0200	MG	BID	URINARY TRACT INFECTION
			PANTOLOC (PANTOPRAZOL)	2011-05-06	2011-05-07		PO	0020	MG	AR	EMESIS

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13FEB2013

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ACI-91	050	21	MOTILIUM (DOMPERIDON)	2011-05-06	2011-05-07		PO	0010	MG	AR	EMESIS
			ASPIRIN (ACETYLSALICYL-S??UR E)	2011-06-10	2011-06-10		PO	500	MG	OAD	HEADACHE
			MEXALEN	2011-10-27	2011-10-28		PO	500	MG	BID	HEADACHE
			METOCLOPRAMID	2011-10-27	2011-10-28		PO	5	MG	BID	EMESIS
			MEXALEN	2011-10-29		YES	PO	500	MG	OAD	HEADACHE
			INFLUENZA VACCINATION	2010-11-24	2010-11-24		IM	0,5	ML	OAD	INFLUENZA VACCINATION
			PARACETAMOL	2011-10-27	2011-10-27		IV	1	G	OAD	HEADACHE
			5 % GLUCOSE	2011-10-27	2011-10-27		IV	500	ML	OAD	EMESIS
			ADJUVIN	2011-04-11	2011-10-24		PO	100	MG	BID	DEPRESSION
			CLARITHROMYCIN	2011-12-08	2011-12-15		PO	500	MG	OAD	COMMON COLD
			PARKEMED	2011-12-08	2011-12-08		PO	500	MG	OAD	COMMON COLD
			AMBROHEXAL	2011-12-08	2011-12-08		PO	30	MG	BID	COMMON COLD
			ADJUVIN	2011-10-24		YES	PO	50	MG	BID	DEPRESSION
			REMINYL RETARD	2011-04-11		YES	PO	16	MG	OAD	AD
	052	21	ARICEPT	2005-02-08		YES	PO	010	MG	OAD	AD
			NEUROBION	2010-09-15		YES	PO	100	MG	OAD	B12 DEFICIENCY

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Listing 16.2.4.4.1: Previous and concomitant medications

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13FEB2013

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ACI-91	052	21	FOLSAN	2010-10-13	2011-11		PO	05	MG	TID	FOLAT DEFICIENCY
			ARICEPT	2003-05-02	2005-02-07		PO	5	MG	OAD	ALZHEIMER'S DISEASE
	055	5	DONEPEZIL	2009-09-01	2009-11-30		PO	0005	MG	OAD	DEMENTIA
			DONEPEZIL	2009-12-01		YES	PO	0010	MG	OAD	DEMENTIA
	057	1	DONEPEZIL	2010-03-29		YES	PO	0010	MG	OAD	ALZHEIMER DESEASE
			VALSARTAN	2009-02		YES	PO	0080	MG	OAD	ARTERIAL HYPERTENSION
			HYDROCHLOROTHIAZID	2009-02		YES	PO	0012.5	MG	OAD	ARTERIAL HYPERTENSION
			CITALOPRAM	2010-03-11	2010-09-20		PO	0010	MG	OAD	DEPRESSION
			CITALOPRAM	2010-09-21		YES	PO	0020	MG	OAD	DEPRESSION
			PSORIASIS CREME	2005		YES	TP	UKN	UKN	AR	PSORIASIS
			(ASS 4,0, SULFUR								
			10,0, RICINUS OIL								
			4,5, ALKALIN COAL.								
			TAR LIQUID 5/0 AD								
			VASELINE 200								
	066	16	ENALAPRIL RATIOPHARM	2000	2011-01-05		PO	10	MG	OAD	ART. HYPERTENSION
			GLIMEPIRID	1990		YES	PO	3	MG	OAD	DIAB. MELLITUS
			METFORMIN	1990		YES	PO	1000	MG	BID	DIAB. MELLITUS

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ACI-91	066	16	LEVOTHYROXIN	2008		YES	PO	100	MCG	OAD	HYPOTHYREOSIS
			DONEPEZIL	2009-12-11	2010-10-12		PO	5	MG	OAD	ALZHEIMER DISEASE
			LANTUS	2000	2011-01-05		SC	40	IU	OAD	DIAB. MELL.
			RISPERIDON	2010-12-14	2011-01-05		PO	1	MG	OAD	AGGRESSION
			LANTUS	2011-01-05		YES	SC	20	IU	OAD	DIABETES MELLITUS
			ENALAPRIL	2011-01-05		YES	PO	5	MG	OAD	HYPERTENSION
			ZOPICLON	2011-01-05		YES	PO	7500	MCG	OAD	SLEEPING DISORDER
			ESCITALOPRAM	2011-01-05		YES	PO	10	MG	OAD	AGGRESSION
			PIPAMPERON	2011-01-05		YES	PO	100	MG	OAD	RESTLESSNESS
			DONEPEZIL	2010-10-13	2010-10-22		PO	10	MG	OAD	ALZHEIMERS DISEASE
			DONEPEZIL	2010-10-23	2011-01-05		PO	5	MG	OAD	ALZHEIMERS DISEASE
			VIT. B12	2010-08		YES	IM	1	U	AR	DECREASE OF VIT B12
			ZOLPIDEM	2010-10-24	2010-11-05		PO	1	TBL	AR	SLEEPING DISORDER
			MELPERON	2010-11-18	2010-11-29		PO	1	TBL	AR	SLEEPING DISORDERS
			FLU VACCINATION	2010-11-09	2010-11-09		SC	UNK	UNK	OAD	PROPHYLAXIS
			LOCAL ANAESTHESIA FOR TOOTH EXTRACTION	2010-11-02	2010-11-02		SC	UNK	UNK	OAD	LOKAL ANESTHESIA
			LORAZEPAME	2011-01-05	2011-01		PO	UNK	UNK	UNK	WORSENING OF AGGRESSION
	067	16	EXELON	2008-04		YES	TP	9500	MCG	OAD	AD

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
ACI-91	067	16	CYMBALTA	2008-10		YES	PO	60	MG	OAD	PROPHYLAXIS OF DEPRESSION
	071	18	TAVOR EXPIDET	2009-07-29		YES	PO	1	MG	AR	ANXIETY REACTION
			REMINYL	2009-10-26		YES	PO	8	MG	OAD	AD
			RAMIPRIL	2007		YES	PO	5	MG	OAD	HYPERTENSION
			SIMVASTATIN	2008-03		YES	PO	20	MG	OAD	HYPERCHOLESTERINEAMIA
			METO HEXAL RETARD	2005		YES	PO	100	MG	OAD	HYPERTENSION
			L-THYROX	1989		YES	PO	75	MCG	OAD	HYPOTHYREOSIS
			DEXAPOS (R) AT	2011-02-07		YES	TP	1	GTT	AR	MACULA EDEMA
			FICORTIL AS	2011-02-07		YES	TP	1	GTT	OAD	MACULA EDEMA
			TRIAMCINOLON	2011-02-07	2011-02-07		IL	UNK	UNK	OAD	MACULA EDEMA
			AMLODIPIN	2011-02-13	2011-02-13		PO	5	MG	OAD	WORSENING HYPERTENSION
	080	13	GALANTAMIN	2010-05	2011-02-26		PO	24	MG	OAD	AD
			DULOXETIN	2008	2011-01-12		PO	30	MG	OAD	DEPRESSION
			DULOXETIN	2011-01-13	2011-02-26		PO	60	MG	OAD	DEPRESSION
			RISPERIDON	2011-02-26		YES	PO	0000.5	MG	BID	PSYCHOSIS
			PIPAMPERON	2011-02-26		YES	PO	20	MG	QID	AGITATION DUE TO PSYCHOSIS

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Listing 16.2.4.4.1: Previous and concomitant medications

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ACI-91	080	13	DULOXETIN	2011-02-27		YES	PO	30	MG	OAD	DEPRESSION
			GALANTAMIN	2011-02-27		YES	PO	16	MG	OAD	AD
			MACROGOL	2011-02-27		YES	PO	0013	G	OAD	OBSTIPATION
			LORAZEPAM	2011-02	2011-03		PO	UNK	UNK	AR	AGITATION DUE TO PSYCHOSIS
	081	17	ZOPICLON	2011-02	2011-03		PO	UNK	UNK	AR	SLEEP DISORDER
			VITAMIN E	2001		YES	PO	0100	MG	OAD	AD
			ASS	2005-06-08		YES	PO	100	MG	OAD	HYPERTENSION
			ARICEPT	2005		YES	PO	10	MG	OAD	AD
	083	17	MOLSIBETA	2000-05-10		YES	PO	8	MG	OAD	PROPHYLAXIS FOR ANGINA P.
			EZETROL	1995-05		YES	PO	10	MG	OAD	HYPERCHOLESTERINEMIA
			IS 5 MONO	1995-06		YES	PO	040	MG	BID	PROPHYLAXIS FOR ANGINA
			ASS	1995-05		YES	PO	100	MG	OAD	PROPHYLAXIS
			METROPOLOL	1998-10		YES	PO	0047.5	MG	OAD	HYPERTENSION
			RAMIPRIL	2000-10-10		YES	PO	10	MG	OAD	HYPERTENSION
			FELODIPIN	2000-10		YES	PO	10	MG	OAD	ESSENTIAL HYPERTONUS
			SPIRONOLACTON	2000-10		YES	PO	25	MG	OAD	HYPERALDOSTERONISM

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Listing 16.2.4.4.1: Previous and concomitant medications

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ACI-91	083	17	SIMVASTATIN	2000-10		YES	PO	80	MG	OAD	HYPERCHOLESTERINEMIA
			ARICEPT	2007-02-09		YES	PO	10	MG	OAD	AD
	087	16	DONEPEZILE	2009-08	2011-03-06		PO	5	MG	OAD	AD
			IRBESARTANE / HCT	2000		YES	PO	150	MG	OAD	ART. HYPERTENSION
			AMLODIPINE	2000		YES	PO	5	MG	OAD	ART. HYPERTENSION
			METFORMIN	2000	2011-08		PO	1000	MG	BID	DIAB. MELL.
			DONEPEZIL	2011-03-07		YES	PO	10	MG	OAD	AD
			METFORMIN	2011-08		YES	PO	500	MG	BID	DIAB. MELL
	089	5	ASS	2007			PO	100	MG	OAD	PROPHYLAXIS
			RAMIPRIL	2007	2011-02-07		PO	10	MG	OAD	ARTERIAL HYPERTENSION
			HYDROCHLORTHIAZID	2007	2011-02-07		PO	25	MG	OAD	ARTERIAL HYPERTENSION
			DULOXETIN	2010-11-20			PO	20	MG	BID	INCONTINENCE
			RAMIPRIL	2011-02-08			PO	05	MG	OAD	ARTERIAL HYPERTENSION
			HYDROCHLORTHIAZID	2011-02-08			PO	013	MG	OAD	ARTERIAL HYPERTENSION
			ARICEPT	2009-09		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
	093	17	EXELON 3 MG	2007-04-12		YES	PO	3	MG	OAD	ALZHEIMER DISEASE
	097	12	L-THYROXIN	2006		YES	PO	0050	MCG	OAD	HYPERTHYREOSIS

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Listing 16.2.4.4.1: Previous and concomitant medications

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ACI-91	097	12	EXELON	2008-12	2009-10		TP	0460	MCG	OAD	ALZHEIMER
			EXELON	2009-10		YES	TP	0950	MCG	OAD	ALZHEIMER
			PENTOHEXAL	2008		YES	PO	0600	MG	OAD	CIRCULATION
			SIMVASTATIN	2003		YES	PO	0030	MG	OAD	HYPERCHOLESTERINEMIA
			CEFUROXIM	2011-02-16	2011-02-20		PO	0500	MG	BID	BRONCHOPULMONAL INFECTION
			ACC	2011-02-16	2011-02-20		PO	0600	MG	OAD	BRONCHOPULMONAL INFECTION
			SULTANOL	2011-02-16	2011-02-18		IH	UNK	UNK	AR	BRONCHOPULMONAL INFECTION
			ATROVENT	2011-02-16	2011-02-18		IH	UNK	UNK	AR	BRONCHOPULMONAL INFECTION
Placebo	001	1	DONEPEZIL	2005-09-29		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			MIRTAZAPIN	2005-09-19		YES	PO	0045	MG	OAD	DEPRESSION
			SIMVASTATIN	2005-07		YES	PO	0040	MG	OAD	HYPERCHOLESTEROLAEMIA
			L-THYROXIN	1996		YES	PO	0100	MCG	OAD	SUBSTITUTION AFTER STRUMECTOMY
			OMEPRAZOL	2001		YES	PO	0040	MG	OAD	REFLUXOESOPHAGITIS
			RAMIPRIL	2009-06-18	2009-06-24		PO	0002.5	MG	OAD	HYPERTENSION
			RAMIPRIL	2009-06-25		YES	PO	0005	MG	OAD	HYPERTENSION

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	001	1	HYDROCHLOROTHIAZID	2009-06-18	2009-06-24		PO	0125	MG	OAD	HYPERTENSION
			HYDROCHLOROTHIAZID	2009-06-25		YES	PO	0025	MG	OAD	HYPERTENSION
			GLASSES	1997		YES					HYPEROPIA BILATERAL
			BISOPROLOL	2010-01-05		YES	PO	0002.5	MG	BID	ESSENTIAL TREMOR
			CIPROFLOXACIN	2010-02-05	2010-02-10		PO	0250	MG	BID	URINAL INFECTION
	003	1	RIVASTIGMIN	2009-01-07	2009-07-03		TRANS-ID	0009.5	MG	OAD	ALZHEIMER DISEASE
			CITALOPRAM	2009-03-02	2009-10-27		PO	0010	MG	OAD	DEPRESSION
			CALCIUM	2003		YES	PO	0500	MG	OAD	OSTEOPOROSIS
			COLECALIFEROL	2003		YES	PO	0010	MCG	OAD	OSTEOPOROSIS
			RIVASTIGMIN	2009-07-04	2009-07-04		PO	0006	MG	OAD	ALZHEIMER DISEASE
			RIVASTIGMIN	2009-07-05	2009-07-05		TRANS-D	0004.6	MG	OAD	ALZHEIMER DISEASE
			RIVASTIGMIN	2009-07-06		YES	TRANS-D	0009.5	MG	OAD	ALZHEIMER DISEASE
			DIMENHYDRINAT	2009-07-03	2009-07-03		PR	0150	MG	OAD	NAUSEA AND EMESIS
			CITALOPRAM	2009-10-28		YES	PO	0020	MG	OAD	DEPRESSION
	005	2	ASS	2001		YES	PO	0100	MG	OAD	PROPHYLAXIS
			ESCITALOPRAM	2008		YES	PO	0020	MG	OAD	DEPRESSIVE SYNDROME
			DONEPEZIL	2008-05-28		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			RAMIPRIL	2005		YES	PO	0005	MG	OAD	ARTERIAL HYPERTENSION
			RISPERDAL	2009-03-04		YES	PO	0003	MG	OAD	ADD-ON

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Listing 16.2.4.4.1: Previous and concomitant medications

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Placebo	005	2	MIRTAZAPINE	2009-03-04	2009-10		PO	0030	MG	OAD	DEPRESSIVE SYNDROME
			MIRTAZAPINE	2009-10		YES	PO	0015	MG	OAD	DEPRESSIVE SYNDROME
	009	1	DONEPEZIL	2008-07-15		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			INSULIN LISPRO 25% SOLUTE CRYSTALSUSPENSION 75% 1ML : 100 IE	2009-07-01		YES	SC	0020	IU	OAD	IDDM
			INSULIN LISPRO 25% SOLUTE CRYSTALSUSPENSION 75% 1ML : 100 IE	2009-07-01		YES	SC	0014	IU	OAD	IDDM
			L-THYROXIN	1999		YES	PO	0100	MCG	OAD	STRUMECTOMY
			SIMVASTATIN	2008-07		YES	PO	0010	MG	OAD	HYPERLIPIDAEMIA
			INFLUENCA VACCINE (HEMAGGLUTININ OF INFLUENCA VIRUS)	2009-09-01			IM	0015	MCG	OAD	INFLUENCA PROPHYLAXIS
	011	1	DONEPEZIL	2008-07-01		YES	PO	0010	MG	OAD	ALZHEIMER DESEASE
			REBOXETIN	2007-06		YES	PO	0004	MG	BID	DEPRESSION
			L-THYROXIN	1990-11		YES	PO	0150	MCG	OAD	THYROIDECTOMY

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Placebo	011	1	CARVEDILOL	2009-01		YES	PO	0006.25	MG	OAD	HIGH BLOOD PRESSURE
			CARVEDILOL	2009-01		YES	PO	0003.125	MG	OAD	HIGH BLOOD PRESSURE
	013	4	DONEPEZIL	2008-06-10		YES	PO	0010	MG	OAD	ALZHEIMER'S DISEASE
			MAGNESIUM	2006		YES	PO	0120	MG	OAD	CRAMPS OF LEGS
	016	4	DONEPEZIL	2009-07		YES	PO	10	MG	OAD	ALZHEIMER\
			VITAMINE B12	2009-08		YES	IM	100	MCG	AR	B12-HYPOVITAMINOSIS
			SIMVASTATIN	2009-11-04		YES	PO	20	MG	OAD	HYPERCHOLESTERINEMIA
			LEVETIRACETAM	2011-03-04	2011-03-18		PO	250	MG	BID	TEMPORAL LOBE EPILEPSY
			LEVETIRACETAM	2011-03-19		YES	PO	500	MG	BID	TEMP. LOBE EPILEPSY
	018	5	L-THYROXIN	2002-08		YES	PO	0075	MCG	OAD	HYPOTHYRIOSIS
			MIRTAZAPIN	2008-08	2010-05-10		PO	0030	MG	OAD	DEPRESSION
			METOHEXAL	2003-06		YES	PO	0100	MG	OAD	HYPERTENSION
			AMLODIPIN	2003-06		YES	PO	0005	MG	OAD	HYPERTENSION
			FEMIKLIMAN UNO	2009-01		YES	PO	6500	MCG	OAD	POST-MENOPAUSAL COMPLAINTS
			REMINYL	2005-07		YES	PO	0024	MG	OAD	DEMENTIA
			MIRTAZAPIN	2010-05-11		YES	PO	0015	MG	OAD	DEPRESSION

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Placebo	018	5	BUPROPION	2010-07-28	2010-08-04		PO	150	MG	OAD	PSYCHMOTORIC DECELERATION
			BUPROPION	2010-08-05		YES	PO	300	MG	OAD	PSYCHMOTORIC DECELERATION
	020	5	LANTUS	1990		YES	IM	0015	IU	OAD	DIABETES
			SIMVASTATIN	2005	2009-07-20		PO	0040	MG	OAD	HYPERCHOLESTERINEMIA
			SIMVASTATIN	2009-07-21		YES	PO	0020	MG	OAD	HYPERCHOLESTERINEMIA
			NOVORAPID	1990		YES	SC	0001.5	IU	AR	DIABETES
			DONEPEZIL	2009-09-24		YES	PO	0010	MG	OAD	DEMENTIA
			FORADIL	2005		YES	IH	0025	MG	OAD	ASTHMA BRONCHALE
			DONEPEZIL	2005-10-18	2007-12-18		PO	0005	MG	OAD	DEMENTIA
	024	4	SIMVASTATIN	2008-11		YES	PO	20	MG	OAD	HYPERCHOLESTERINEMIA
			ENALAPRIL	2008-11		YES	PO	5	MG	OAD	HYPERTENSION
			THYROXIN	2008-11		YES	PO	75	MCG	OAD	THYROID INSUFFICIENCY
			VITAMIN B12 AND FOLIC ACID	2009	2009		PO	400	MG	OAD	HYPERHOMOCYSTEINEMIA
			ALFUZOSIN	2010-09-16		YES	PO	10	MG	OAD	PROSTATA HYPERPLASIA
			CLINDAMYCIN	2011-01-28	2011-02-01		PO	600	MG	BID	DENTAL INFECTION
			RIVASTIGMIN (EXELON)	2008-11-12	2008-12-15		TP	0004.6	MG	OAD	DEMENTIA

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Placebo	024	4	RIVASTIGMIN (EXELON) TRANSDERMAL, PATCHES	2008-12-15		YES	TP	0009.5	MG	OAD	DEMENTIA
	028	20	EXELON PFLASTER	2010-07-01	2010-07-18		TP	0004.6	MG	OAD	AD
			CYMBALTA	2010-06-15		YES	PO	60	MG	OAD	AD
			MAGNOSOLV	2009		YES	PO	0006.1	G	OAD	CRAMP IN THE CALF
			EXELON PFLASTER	2010-07-19		YES	TP	0009.5	MG	OAD	AD
			AVANIC	2011-03-05	2011-03-11		IV	500	MG	TID	PNEUMONIA
			TAVANIC	2011-03-12	2011-03-17		PO	500	MG	OAD	PNEUMONIA
			PANTOLOC	2011-03-05		YES	PO	20	MG	OAD	GASTRIC PROTECTION
			TAVIPEC	2011-03-05	2011-03-17		PO	0000.15	G	OAD	PNEUMONIA
			MUCOBENE	2011-03-11	2011-03-17		PO	600	MG	OAD	PNEUMONIA
			FORLAX	2011-03-06		YES	PO	10	G	OAD	OBSTIPATION
	029	8	DONEZEPIL	2009-10-29	2010-01-28		PO	5	MG	OAD	ALZHEIMER
			BENZBROMARON	2001		YES	PO	100	MG	OAD	HYPERURICAEMIA, EVERY 2. DAY
			CAPTOPRIL	2003-07		YES	PO	0012.5	MG	OAD	ART. HYPERTENSION
			L-THYROXIN	1993		YES	PO	50	MCG	OAD	HYPOTHYREAOISIS
			SIMVASTATIN	2008-04		YES	PO	10	MG	OAD	HYPERLIPIDEMIA

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	029	8	METFORMIN	2008-04	2010-08-13		PO	250	MG	BID	DIABETES MELLITUS
			METOHEXAL	1993		YES	PO	25	MG	OAD	ART. HYPERTENSION
			CRANBEROLA	2001		YES	PO	1	CAP	OAD	BLADDER PROPHYLAXIS
			LINIMENT	2010-01-28	2010-01-29		ID	2	MG	BID	PAIN IN THE THENAR
			PANTOPRAZOL	2010-02-03	2010-02-10		PO	20	MG	OAD	GASTRITIS
			DONEPEZIL	2010-01-29		YES	PO	10	MG	OAD	ALZHEIMER
			PARACETAMOL	2010-01-30	2010-02-23		PO	500	MG	AR	HEADACHE (RECURRENT)
			PARACETAMOL	2010-01-30	2010-01-30		PO	500	MG	AR	SHOULDER + NECK PAIN
			GEH-WOHL-FOOTBATH	2010-01-29	2010-01-29		ID	2000	ML	AR	CRAMP IN THE CALF
			PETROLIUM JELLY	2010-01-29	2010-01-29		ID	02	G	AR	CRAMP IN THE CALF
			TALCID	2010-02-10	2010-02-10		PO	500	MG	OAD	GASTRITIS + VOMITING
			PANTOPRAZOL	2010-04-23	2010-04-23		PO	020	MG	OAD	RECURRENT STOMACHE PAIN
			PARACETAMOL	2010-04-27	2010-04-27		PO	500	MG	BID	HEADACHE (RECURRENT)
			PANTOPRAZOL	2010-04-25	2010-04-25		PO	020	MG	OAD	RECURRENT STOMACHE PAIN
			METFORMIN	2010-08-14		YES	PO	250	MG	OAD	DIABETES MELLITUS
			OFLOXIN	2010-08-11	2010-08-13		PO	100	MG	BID	URINARY TRACT INFECTION
			TALCID	2010-08-24	2010-08-24		PO	100	MG	OAD	FEELING OF FULLNESS

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	029	8	OFLOXIN	2010-10-03	2010-10-06		PO	100	MG	BID	URINARY TRACT INFECTION
			PARACETAMOL	2010-02-01	2010-02-01		PO	500	MG	OAD	RINGING IN THE EARS
			PARACETAMOL	2010-10-14	2010-10-14		PO	500	MG	OAD	HEADACHE
	031	8	SIMVASTATIN	2009-10-06		YES	PO	40	MG	OAD	HYPERCHOLESTERINEMIA
			REMINYL	2009-10-06		YES	PO	24	MG	OAD	AD
			NAPROXEN	2010-10-26	2010-11-30		PO	250	MG	AR	SCAPULA PAIN
			PROCAIN 2%	2010-10-26	2010-10-26		IM	10	ML	AR	SCAPULA PAIN
			GABAPENTIN	2010-10-28	2010-11-02		PO	100	MG	AR	SCAPULA PAIN
			IBUPROFEN	2010-11-03	2010-11-30		PO	800	MG	AR	SCAPULA PAIN
			GABAPENTIN	2010-11-03	2010-11-30		PO	300	MG	AR	SCAPULA PAIN
			XYLONEST 1% + TRIAM	2010-11-30	2010-11-30		IM	10	MG	OAD	SHOULDER PAIN SCAPULA
			ZOLPIDEM	2011-05-21	2011-05-31		PO	0010	MG	OAD	INSOMNIA
			HALOPERIDOL	2011-06-01	2011-06-01		PO	0001	MG	OAD	INSOMNIA
			MIRTAZAPIN	2011-06-06	2011-06-06		PO	0015	MG	OAD	INSOMNIA
			MIRTAZAPIN	2011-06-07		YES	PO	7500	MCG	OAD	INSOMNIA
	034	9	EXELON PATCH	2009-05		YES	TP	0009.5	MG	OAD	DEMENTIA
	041	12	GALANTAMIN	2008-07-24		YES	PO	0024	MG	OAD	ALZHEIMER

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	041	12	ASS	1989		YES	PO	0300	MG	OAD	CEREBRAL ISCHAEMIA
			DICLOFENAC	2009-07	2009-10-17		PO	0075	MG	TID	KNEE PAIN
			OMEPRAZOL	2009-10-17	2009-11-03		PO	0020	MG	BID	GASTRITIS
			NOVAMINSULFON	2009-10-17		YES	PO	0500	MG	BID	KNEE PAIN
			ENALAPRIL	2010-01-11	2010-02		PO	0010	MG	OAD	ATERIAL HYPERTONIA
			GALANTAMIN	2007-02-12	2007-04-02		PO	0008	MG	OAD	ALZHEIMER
			GALANTAMIN	2007-04-03	2007-07-23		PO	0016	MG	OAD	ALZHEIMER
			ENALAPRIL	2010-02		YES	PO	0020	MG	OAD	ARTERIAL HYPERTENSION
	044	12	SIMVASTATIN	2007-11		YES	PO	0020	MG	OAD	HYPERCHOLESTERINEMIA
			CARVEDILOL-1A	2007-11		YES	PO	0025	MG	OAD	ARTERIAL HYPERTENSION
			ISDN-RATIOPHARM	2007-11		YES	PO	0060	MG	BID	ARTERIAL HYPERTENSION
			TORASEMID-RATIOPHARM	2009-11		YES	PO	0005	MG	OAD	ARTERIAL HYPERTENSION
			REMINYL	2008-01-30		YES	PO	0016	MG	OAD	AD
			REMINYL	2007-12-03	2008-01-29		PO	0008	MG	OAD	AD
			ALLOPURINOL	2007-11		YES	PO	0300	MG	OAD	HYPERURICAEMIA
	045	11	ASS	2007		YES	PO	100	MG	OAD	PROPHYLAXIS
			ALISKREN	2007		YES	PO	150	MG	BID	HYPERTONIA
			ROSUVASTATIN	2007		YES	PO	20	MG	OAD	HYPERCHOLESTERINEMIA
			TEBONIN	2007	2009-11-04		PO	120	MG	BID	DEMENTIA

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	045	11	DONEPEZIL	2009-04		YES	PO	10	MG	OAD	DEMENTIA
			CITALOPRAM	2010-09-07		YES	PO	20	MG	OAD	MOTIVATION
	047	11	L-THYROXIN	2009-08		YES	PO	25	MG	OAD	HYPOTHYREOSIS
			METOPROLOL	2005-03		YES	PO	47	MG	OAD	HYPERTENSION
			ASPIRIN	2005-03		YES	PO	100	MG	OAD	THROMBOCYTE AGGREGATION PROPHYLAXIS
			RIVASTIGMIN	2008-08		YES		0009.5	MG	OAD	DEMENTIA
			CANDESARTAN	2005-03		YES	PO	8	MG	OAD	HYPERTENSION
			FLUVASTATINE	2005-03		YES	PO	80	MG	OAD	HYPERCHOLESTERINEMIA
			VITAMINE B12	2009-08		YES	PO	10	MG	OAD	HYPOVITAMINOSIS
	049	21	RISPERIDON	2010-08	2011-07-27		PO	1	MG	BID	BEHAVIOURAL DISORDER
			SEROPRAM	2006-11-16		YES	PO	20	MG	OAD	DEPRESSION
			AMLODIPIN	2006		YES	PO	5	MG	OAD	HYPERTENSION
			ZOROXIN	2010-10-26	2010-11-04		PO	400	MG	BID	URINARY TRACT INFECTION
			URIVESC	2010-10-24	2010-10-29		PO	60	MG	OAD	URINARY TRACT INFECTION

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	049	21	ZOROXIN	2010-11-12	2010-11-21		PO	400	MG	BID	URINARY TRACT INFECTION
			URIVESC	2011-04-12	2011-04-22		PO	60	MG	OAD	URINARY TRACT INFECTION
			LASIX, FUROSEMID	2009-09-04	2011-01-17		PO	20	MG	OAD	HYPERTENSION
			INKONTAN	2011-01-18	2011-03-30		PO	30	MG	BID	POLLAKISURIA
			ACETYLSALICYLSAEURE, ASCORBINSAEURE	2011-01-30	2011-01-30		PO	500	MG	OAD	COLD
			ZYPREXA	2011-07-22	2011-07-23		PO	0002.5	MG	BID	BEHAVIOURAL DISEASE
			CIPROXIN	2011-07-23	2011-08-01		PO	250	MG	BID	URINARY TRACT INFECTION
			EXELON	2011-08-29		YES	PO	0004.5	MG	BID	ALZHEIMER'S DISEASE
			TRITTICO	2011-08-13	2011-08-24		PO	100	MG	BID	BEHAVIOURAL DISEASE
			TEMESTA	2011-08-24		YES	PO	0000.5	MG	TID	BEHAVIOURAL DISEASE
			EXELON	2008-01-17	2011-08-23		PO	0004.5	MG	BID	ALZHEIMER'S DISEASE
			NITROFURANTOIN	2011-10-13	2011-10-19		PO	50	MG	BID	URINARY TRACT INFECTION
			OXYBUTININ	2011-08-02	2011-08-04		TP	0003.9	MG	OAD	POLLAKISURIA
			LUTAMAX	2010-10-27	2011-07-05		PO	10	MG	OAD	MACULA PROPHYLAXIS
			DITROPAN	2011-05-07	2011-07-20		PO	5	MG	AR	POLLAKISURIA
			TRITTICO	2011-08-08	2011-08-12		PO	50	MG	BID	BEHAVIOURAL DISEASE

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	049	21	OLEOVIT	2011-08-24		YES	PO	8000	IU	AR	VITAMIN D3 DEFICIENCY
			LOVENOX	2011-09-10	2011-10-14		SC	80	MG	BID	PELVIC VEIN THROMBOSIS
			RISPERDAL QL	2011-09-06		YES	PO	1	MG	BID	BEHAVIOURAL DISEASE
			NEUROBION	2011-09-06	2011-10-14		PO	100	MG	OAD	VIT B12 DEFICIENCY
			KALI-ORAL	2011-09-06	2011-10-14		PO	8	G	OAD	POTASSIUM DEFICIENCY
			SEROQUEL	2011-09-06	2011-10-14		PO	100	MG	OAD	BEHAVIOURAL DISEASE
			TRIPRIM	2011-09-28	2011-10-03		PO	200	MG	BID	URINARY TRACT INFECTION
	051	21	REMINYL	2009-09-29		YES	PO	16	MG	OAD	AD
			EUTHYROX	2008-10-03	2011-02-01		PO	75	MCG	OAD	HYPOTHYROIDISM
			LESCOL MR, FLUVASTATIN	2009		YES	PO	080	MG	OAD	HYPERCHOLESTEROLAEMIA
			EUTHYROX	2011-02-02	2011-08-30		PO	100	MCG	OAD	HYPOTHYROIDISM
			REMINYL	2009-09-01	2009-09-28		PO	8	MG	OAD	ALZHEIMER'S DISEASE
			EUTHYROX	2011-08-31		YES	PO	75	MCG	OAD	HYPOTHYROIDISM
			THIAMAZOL	2008-05-30	2008-09-16		PO	10	MG	OAD	STRUMA MULTINODUSA, HYPERTHYROIDISM
	056	5	ASS	2001	2010-05-03		PO	0100	MG	OAD	ANTICOAGULATION

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Listing 16.2.4.4.1: Previous and concomitant medications

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Placebo	056	5	ATENOLOL	2005		YES	PO	0050	MG	OAD	ARTERIAL HYPERTENSION
			DONEPEZIL	2009-03-05		YES	PO	0010	MG	OAD	DEMENTIA
			DONEPEZIL	2009-02-06	2009-03-04		PO	0005	MG	OAD	DEMENTIA
			TILIDIN	2010-05-03	2010-05-27		PO	0050	MG	BID	SPINAL CANAL STENOSIS
			ALENDRONIC ACID	2009-09		YES	PO	0070	MG	OAW	OSTEOPOROSIS
			NALOXON	2010-05-03	2010-05-27		PO	0004	MG	BID	SPINAL CANAL STENOSIS
			IBUPROFEN	2010-06-30	2010-10-10		PO	600	MG	TID	CHRONICAL PAIN, LUMBOISCHIALGIA
			FRAXIPARIN	2010-07-01	2010-07-05		SC	0000.3	ML	OAD	POST SURGERY SPINAL CANAL STENOSIS
			TILIDIN	2010-05-28	2010-06-30		PO	200	MG	BID	CHRONICAL PAIN
			NALOXON	2010-05-28	2010-06-30		PO	16	MG	BID	CHRONICAL PAIN
			METAMIZOL	2010-09-14	2010-10-10		PO	500	MG	AR	CHRONICAL PAIN
			IBUPROFEN	2010-10-11		YES	PO	600	MG	AR	CHRONICAL PAIN
			METAMIZOL	2010-10-11		YES	PO	500	MG	OAD	CHRONICAL PAIN
	058	1	DONEPEZIL	2010-05-15		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			RAMIPRIL	2011-03-23		YES	PO	0005	MG	OAD	HIGH BLOOD PRESSURE
			AZITROMYCIN	2011-10-13	2011-10-16		PO	500	MG	OAD	SINUSITIS
			ASPIRIN + C	2011-06-04	2011-06-10		PO	500	MG	AR	COLD

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Placebo	059	1	DONEPEZIL	2010-08-20		YES	PO	0010	MG	OAD	ALZHEIMER DISEASE
			RAMIPRIL	2010-05		YES	PO	0010	MG	OAD	ARTERIAL HYPERTENSION
			IBUPROFEN	2010-12-31		YES	PO	0400	MG	AR	PAIN OF THE ACHILLES TENDON, RIGHT SIDE
			ASS	2011-02-13	2011-02-15		PO	0500	MG	BID	INFLUENZAL INFECTION
			ACICLOVIR	2011-06-03	2011-06-09		PO	0125	MG	OAD	HERPES ZOSTER
			ASS 500	2011-05-31	2011-05-31		PO	0500	MG	OAD	HEADACHE
			ACICLOVIR	2011-06-03	2011-06-09		PO	0125	MG	OAD	HERPES ZOSTER
			CITALOPRAM	2011-09-09		YES	PO	10	MG	OAD	DEPRESSION
			IBUPROFEN	2011-09-13	2011-09-17		PO	0400	MG	OAD	LUMBOISCHIALGIA
			PREDNISOLON	2011-09-14	2011-09-16		IM	0025	MG	OAD	LUMBOISCHIALGIA
			MAGNETRANS FORTE	2011-07-17		YES	PO	0150	MG	BID	FOOD SUPPLEMENT
	065	16	ASS	2007	2010-08-27		PO	100	MG	OAD	Z.N. VORHOFFLIMMERN (ATRIAL FIBRILLATION)
			RAMIPRIL COMP 5/25MG	2000		YES	PO	1	TBL	BID	ATR. HYPERTENSION
			BISOPROLOL	2000		YES	PO	5	MG	BID	ART. HYPERTENSION
			REMINYL (GALANTAMIN)	2010-02-03		YES	PO	16	MG	OAD	ALZHEIMER DISEASE
			GLIMEPIRID	2000		YES	PO	1	MG	OAD	DIABETES MELLITUS
			ASS	2010-08-31		YES	PO	100	MG	OAD	ARTRI. FIBRILLATION
			BIFITERAL	2011-04		YES	PO	20	ML	OAD	OBSTIPATION

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13FEB2013

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Placebo	065	16	NEUROTRAT S FORTE	2011-03-16		YES	PO	1	TBL	TID	ALCOHOL DEPENDENCY
			SIMVASTATIN	2011-04		YES	PO	20	MG	OAD	HYPERLIPIDEMIA
			RISPERIDON	2011-04		YES	PO	2500	MCG	BID	ALZHEIMERS DISEASE
	068	16	THYRONAJOD	1989		YES	PO	75	MCG	OAD	STRUMA
			ASS	2008		YES	PO	100	MG	OAD	PROPHYLAXIS OF INTERMITTENT ATRIAL FIBRILATION
			SIMVASTATIN	2003		YES	PO	20	MG	OAD	HYPERLIPIDAEMIA
			MICARDIS	2003		YES	PO	40	MG	OAD	ART. HYPERTENSION
			DEXPANTHENOL	2009-02		YES	CONJ. TP	UNK	GTT	OAD	OPEN-ANGLE-GLAUCOMA
			LUMIGAN	2008-03		YES	CONJ. TP	1- 2	GTT	OAD	OPEN-ANGLE-GLAUCOMA
			EXELON	2008		YES	TP	9500	MCG	OAD	ALZHEIMER DISEASE
	069	23	ACECOMB 2X1	1990-10-01	2011-12-15		PO	01	TBL	BID	HYPERTENSION
			KREON	2007-10-01	2011-12-15		PO	01	TBL	TID	PANCREAS ENZYME DEFECT
			ANTIBIOPHILUS	2007-10-01	2011-12-15		PO	01	TBL	TID	PANCREAS ENZYME DEFECT
			NOMEXOR	1990-10-01	2011-12-15		PO	5	MG	OAD	HYPERTENSION

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	069	23	TAMSULOSIN	2011-12-16		YES	PO	0000.4	MG	OAD	PROSTATIC HYPERTROPHIE
			OLMESARTANMEDOXOMIL	2011-12-16		YES	PO	40	MG	OAD	HYPERTENSION
			AMLODIPINBESILAT	2011-12-16		YES	PO	5	MG	OAD	HYPERTENSION
			HYDROCHLOROTHIAZID	2011-12-16		YES	PO	0012.5	MG	OAD	HYPERTENSION
			ARICEPT	2010-02-17	2010-03-18		PO	5	MG	OAD	DEMENTIA
			ARICEPT	2010-03-19		YES	PO	10	MG	OAD	DEMENTIA
			AMLODIPINBESILAT	2011-12-16		YES	PO	5	MG	OAD	HYPERTENSION
			HYDROCHLOROTHIAZID	2011-12-16		YES	PO	125	MG	OAD	HYPERTENSION
			ARICEPT	2010-02-17	2010-03-18	YES	PO	5	MG	OAD	DEMENTIA
			ARICEPT	2010-03-19		YES		110	MG	OAD	DEMENTIA
	072	18	PRAVASTATIN	2009-11		YES	PO	10	MG	OAD	HYPERCHOLESTERINAEMIA
			METOPROLOL	2000-11		YES	PO	25	MG	OAD	HYPERTENSION
			TROMCARDIN	2006-06		YES	PO	1	MG	BID	CORONAR HEART DISEASE
			MAGNESIUM VERLA	2009-03-16		YES	PO	90	MG	OAD	COXARTHROSIS
			RAMITIDIN	2010-06-01		YES	PO	150	MG	OAD	HYPERTENSION
			ARICEPT	2008-08-07		YES	PO	10	MG	OAD	AD
	079	13	TREVILOR RETARD	2008-05		YES	PO	0075	MG	BID	DEPRESSION
			SORTIS	2003		YES	PO	0020	MG	OAD	HYPERCHOLESTERINEMIA

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	079	13	BELOC ZOK	2003		YES	PO	0095	MG	OAD	HYPERTENSION
			ARICEPT	2008-05		YES	PO	0010	MG	OAD	ALZHEIMER
			JODID	1990		YES	PO	0200	MCG	OAD	PROPHYLAXIS
			ASA	2010-11-05	2010-11-30		PO	500	MG	AR	COMMON COLD
	082	17	METOPROLOL	2005-12-15		YES	PO	0025.5	MG	OAD	HYPERTENSION
			RAMIPRIL	2006-01-28		YES	PO	0002.5	MG	OAD	HYPERTENSION
			REMINYL	2008-05-13		YES	PO	24	MG	OAD	AD
	084	17	LISI-HEXAL	2000-08		YES	PO	5	MG	OAD	HYPERTENSION
			ASS	2000-08		YES	PO	100	MG	OAD	HYPERTENSION
			ARICEPT	2010-05-28		YES	PO	10	MG	OAD	DAT
			PANTOPRAZOL	2010-05-28		YES	PO	20	MG	OAD	CARDIALGIA
			SIMVASTATIN	2008-08		YES	PO	20	MG	OAD	HYPERCHOLESTERIN??MIA
	086	21	ARICEPT	2008-01-16		YES	PO	10	MG	OAD	AD
			THYREX	2003-10-29		YES	PO	100	MCG	OAD	HYPOTHYROIDISM
			SEROPRAM	2003-10-29		YES	PO	10	MG	OAD	DEPRESSION
			THROMBO ASS	2010-07-06		YES	PO	100	MG	OAD	CARDIOVASCULAR
			FOSAMAX	2006-09-29		YES	PO	70	MG	AR	OSTEOPOROSIS

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	086	21	ENALAPRILMALEAT (CO RENITEC)	2003-10-29		YES	PO	20	MG	OAD	HYPERTENSION
			HYDROCHLORTHIAZID	2010-10-04		YES	PO	0012.5	MG	OAD	HYPERTENSION
			PROXEN	2010-12-02	2010-12-02		PO	500	MG	OAD	COMMON COLD
			ARICEPT	2007-07-05	2008-01-16		PO	5	MG	OAD	ALZHEIMER'S DISEASE
	088	16	GALANTAMINE	2007		YES	PO	16	MG	OAD	ALZHEIMERS DISEASE
			"REMINYL"								
			RISPERIDONE	2010	2011-02-12		PO	500	MCG	OAD	ALZHEIMERS DISEASE
			SILYMARIN	2007		YES	PO	86,5	MG	OAD	PROPHYLAXIS AGAINST LIVER DAMAGE
			IBUPROFENE	2000		YES	PO	800	MG	AR	CERVICAL DEGENERATIO
			DIMENHYDRINATE / (ARLEVERT)	2008		YES	PO	20	MG	AR	CERVICAL DEGENERATIO
			L-THYROXIN	2008	2011-08-10		PO	100	MCG	OAD	HYPOTHYREOSIS
			MELPERON	2011-05-04	2011		PO	12,5	MG	BID	AGITATION / AGGRESSION
			RISPERIDONE	2011-02-13	2011-08-10		PO	1500	MCG	OAD	ALZHEIMERS DISEASE
			CINARICINE	2008		YES	PO	40	MG	AR	CERVICAL DEGENERATION
			RISPERIDONE	2011-08-10		YES	PO	500	MCG	OAD	ALZHEIMER DISEASE
			L-THYROXINE	2011-08-10		YES	PO	75	MCG	OAD	HYPOTHYREOSIS

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Listing 16.2.4.4.1: Previous and concomitant medications

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Treat- ment	Random No.	Site ID	Medication/therapy	Start date [YYYY-MM-DD]	Stop date [YYYY-MM-DD]	On- go- ing	Route	Dose	Unit	Fre- quen- cy	Indication
Placebo	088	16	QUETIAPINE	2011-08-01	2011-08-07		PO	12,5	MG	OAD	ALZHEIMER DISEASE
			QUETIAPINE	2011-08-08	2011-08-15		PO	25	MG	FTD	ALZHEIMER DISEASE
			QUETIAPINE	2011-08-16		YES	PO	050	MG	FTD	ALZHEIMER DISEASE
			TREVILOR	2004	2008		PO	75	MG	OAD	AGGRESSION
			MELPERON	2011	2011-08-15		PO	25	MG	OAD	AGITATION + AGGRESSION
			MELPERON	2011	2011-08-15		PO	50	MG	OAD	AGITATION + AGGRESSION
			MELPERON	2011-08-23		YES	PO	50	MG	OAD	AGITATION + AGGRESSION

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
(BETRAFEN GEL)	UNK	UNK	TP	TINEA PEDIS	D01AE	OTHER ANTIFUNGALS	ANTIFUNGALS FOR
CICLOPIROX						FOR TOPICAL USE	DERMATOLOGICAL USE
5 % GLUCOSE	500	ML	IV	EMESIS	B05CX	OTHER IRRIGATING	BLOOD SUBSTITUTES
						SOLUTIONS	AND PERFUSION
ACC	0600	MG	PO	BRONCHOPULMONAL	R05CB	MUCOLYTICS	SOLUTIONS
				INFECTION			COUGH AND COLD
ACECOMB 2X1	01	TBL	PO	HYPERTENSION	C09BA	ACE INHIBITORS AND	PREPARATIONS
						DIURETICS	AGENTS ACTING ON
							THE
ACETYLSALICYLSAEURE,	500	MG	PO	COLD	N02BA	SALICYLIC ACID AND	RENIN-ANGIOTENSIN
ASCORBINSAEURE						DERIVATIVES	SYSTEM
ACICLOVIR	0125	MG	PO	HERPES ZOSTER	D06BB	ANTIVIRALS	ANALGESICS
							ANTIBIOTICS AND
ACTONEL	35	MG	PO	OSTEOPOROSIS	M05BA	BISPHOSPHONATES	CHEMOTHER. FOR
							DERMATOLOGICAL USE
ADJUVIN	100	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN	DRUGS FOR TREATMENT
						REUPTAKE INHIBITORS	OF BONE DISEASES
ADJUVIN	50	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN	PSYCHOANALEPTICS
						REUPTAKE INHIBITORS	
ADJUVIN, SERTRALIN	50	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN	PSYCHOANALEPTICS
						REUPTAKE INHIBITORS	

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
ADVANTAN CREME			TP	ATOPIC DERMATITIS	D07AC	CORTICOSTEROIDS, POTENT (GROUP III)	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
ALENDRONIC ACID	0070	MG	PO	OSTEOPOROSIS	M05BA	BISPHOSPHONATES	DRUGS FOR TREATMENT OF BONE DISEASES
ALFUZOSIN	10	MG	PO	PROSTATA HYPERPLASIA	G04CA	ALPHA-ADRENORECEPTOR ANTAGONISTS	UROLOGICALS
ALISKREN	150	MG	PO	HYPERTONIA	C09XA	RENIN-INHIBITORS	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
ALLOPURINOL	0100	MG	PO	HYPERURICAEMIA	M04AA	PREPARATIONS INHIBITING URIC ACID PRODUCTION	ANTIGOUT PREPARATIONS
ALLOPURINOL	0300	MG	PO	HYPERURICAEMIA	M04AA	PREPARATIONS INHIBITING URIC ACID PRODUCTION	ANTIGOUT PREPARATIONS
ALLOPURINOL	0300	MG	PO	HYPERURICAEMIA	M04AA	PREPARATIONS INHIBITING URIC ACID PRODUCTION	ANTIGOUT PREPARATIONS
ALLOPURINOL	100	MG	PO	HYPERURICAEMIA	M04AA	PREPARATIONS INHIBITING URIC ACID PRODUCTION	ANTIGOUT PREPARATIONS
ALUMINA GLOBULI	3	CAP	PO	DISCOMFORT, MALAISE	A02AB	ALUMINIUM COMPOUNDS	DRUGS FOR ACID RELATED DISORDERS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
AMBROHEXAL	30	MG	PO	COMMON COLD	R05CB	MUCOLYTICS	COUGH AND COLD PREPARATIONS
AMLODIPIN	0005	MG	PO	HYPERTENSION	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS
AMLODIPIN	5	MG	PO	HYPERTENSION	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS
AMLODIPIN	5	MG	PO	WORSENING HYPERTENSION	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS
AMLODIPINBESILAT	5	MG	PO	HYPERTENSION	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS
AMLODIPINE	5	MG	PO	ART. HYPERTENSION	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS
ANTIBIOPHILUS	01	TBL	PO	PANCREAS ENZYME DEFECT	A07FA	ANTIDIARRHEAL MICROORGANISMS	ANTIDIARR., INTEST. ANTIINFL./ANTIINFECT. AGENTS
ARICEPT	0005	MG	PO	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	0010	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	0010	MG	PO	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	0010	MG	PO	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	0010	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	010	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	10	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	10	MG	PO	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	10	MG	PO	DAT	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	10	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
ARICEPT	110	MG		DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	5	MG	PO	ALZHEIMER'S DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	5	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ARICEPT	5	MG	PO	PROPHYLAXIS	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
				ALZHEIMER DISEASE			
ARICEPT	6	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ASA	500	MG	PO	COMMON COLD	N02BA	SALICYLIC ACID AND DERIVATIVES	ANALGESICS
ASPIRIN	100	MG	PO	THROMBOCYTE AGGREGATION PROPHYLAXIS	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASPIRIN (ACETYLSALICYL-S??URE)	500	MG	PO	HEADACHE	N02BA	SALICYLIC ACID AND DERIVATIVES	ANALGESICS
ASPIRIN + C	500	MG	PO	COLD	N02BA	SALICYLIC ACID AND DERIVATIVES	ANALGESICS
ASS	0100	MG	PO	ANTICOAGULATION	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS	0100	MG	PO	CARDIAC PROPHYLAXIS	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
ASS	0100	MG	PO	PROPHYLAXIS	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS	0300	MG	PO	CEREBRAL ISCHAEMIA	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS	0500	MG	PO	HEADACHE	N02BA	SALICYLIC ACID AND DERIVATIVES	ANALGESICS
ASS	0500	MG	PO	INFLUENZAL INFECTION	N02BA	SALICYLIC ACID AND DERIVATIVES	ANALGESICS
ASS	100	MG	PO	ARTRI. FIBRILLATION	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS	100	MG	PO	HYPERTENSION	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS	100	MG	PO	PROPHYLAXIS	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
ASS	100	MG	PO	PROPHYLAXIS OF INTERMITTENT ATRIAL FIBRILATION	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS	100	MG	PO	Z.N. VORHOFFLIMMERN (ATRIAL FIBRILLATION)	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS 100	0100	MG	PO	CORONARY HEART DISEASE	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS 100	100	MG	PO	MICROANGIOPATHY	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
ASS 500	0500	MG	PO	HEADACHE	N02BA	SALICYLIC ACID AND DERIVATIVES	ANALGESICS
ATENOLOL	0050	MG	PO	ARTERIAL HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
ATROVENT	UNK	UNK	IH	BRONCHOPULMONAL INFECTION	R03BB	ANTICHOLINERGICS	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
AUGMENTIN	1000	MG	PO	URINARY TRACT INFECTION	J01CR	COMB OF PENICILLINS, INCL. BETA-LACTAMASE INHIB.	ANTIBACTERIALS FOR SYSTEMIC USE
AVANIC	500	MG	IV	PNEUMONIA	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE
AZITROMYCIN	500	MG	PO	SINUSITIS	J01FA	MACROLIDES	ANTIBACTERIALS FOR SYSTEMIC USE
BALDRIAN	1	TBL	PO	INSOMNIA	V90		UNSPECIFIED HERBAL
BELOC ZOK	0095	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE PREPARATIONS	BETA BLOCKING AGENTS
BENZBROMARON	100	MG	PO	HYPERURICAEMIA, EVERY 2. DAY	M04AB	INCREASING URIC ACID EXCRETION	ANTIGOUT PREPARATIONS
BETAHISTIN AL	12	MG	PO	VERTIGO	N07CA	ANTIVERTIGO PREPARATIONS	OTHER NERVOUS SYSTEM DRUGS
BETAMETHASONDIPROPION AT (LOTTRICOMB)	0640	MCG	TP	INGUINAL INTERTRIGO	D07AC	CORTICOSTEROIDS, POTENT (GROUP III)	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
BIFITERAL	20	ML	PO	OBSTIPATION	A06AD	OSMOTICALLY ACTING LAXATIVES	LAXATIVES
BISOPROLOL	0001.25	MG	PO	HIGH BLOOD PRESSURE	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
BISOPROLOL	0002.5	MG	PO	ESSENTIAL TREMOR	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
BISOPROLOL	5	MG	PO	ART. HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
BUPROPION	0150	MG	PO	APATHY	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
BUPROPION	0300	MG	PO	APATHY	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
BUPROPION	150	MG	PO	PSYCHMOTORIC DECELERATION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
BUPROPION	300	MG	PO	PSYCHMOTORIC DECELERATION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
BUPROPION	0150	MG	PO	APATHY	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
CALCIUM	0500	MG	PO	OSTEOPOROSIS	A12AA	CALCIUM	MINERAL SUPPLEMENTS
CANDESARTAN	0004	MG	PO	ART. HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
CANDESARTAN	16	MG	PO	HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
CANDESARTAN	8	MG	PO	ART. HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

NK/UNK/UKN=not known, OAD=once a day, AR=as required, BID=twice a day, TID=three times a day

PO=oral, TP=topical, IV=intravenous, ID=intradermal, IM=intramuscular, SC=subcutaneous

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
CANDESARTAN	8	MG	PO	HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
CAPTOPRIL	0012.5	MG	PO	ART. HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
CARVEDILOL	0003.125	MG	PO	HIGH BLOOD PRESSURE	C07AG	ALPHA AND BETA BLOCKING AGENTS	BETA BLOCKING AGENTS
CARVEDILOL	0006.25	MG	PO	HIGH BLOOD PRESSURE	C07AG	ALPHA AND BETA BLOCKING AGENTS	BETA BLOCKING AGENTS
CARVEDILOL-1A	0025	MG	PO	ARTERIAL HYPERTENSION	C07AG	ALPHA AND BETA BLOCKING AGENTS	BETA BLOCKING AGENTS
CEFUROXIM	0500	MG	PO	BRONCHOPULMONAL INFECTION	J01DC	SECOND-GENERATION CEPHALOSPORINS	ANTIBACTERIALS FOR SYSTEMIC USE
CEREBOKAN	80	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
CINARICINE	40	MG	PO	CERVICAL DEGENERATION	N07CA	ANTIVERTIGO PREPARATIONS	OTHER NERVOUS SYSTEM DRUGS
CIPRAMIL	0020	MG	PO	DEPRESSIVE SYMPTOMS	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CIPROFLOX	500	MG	PO	MILD BLADDER INFECTION	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE
CIPROFLOXACIN	0250	MG	PO	URINAL INFECTION	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
CIPROXIN	250	MG	PO	URINARY TRACT INFECTION	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE
CITALOPRAM	0010	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CITALOPRAM	0020	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CITALOPRAM	0020	MG	PO	DEPRSSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CITALOPRAM	0020	MG	PO	LOSS OF INTRA-INDIVIDUAL ACTIVITY	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CITALOPRAM	10	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CITALOPRAM	20	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CITALOPRAM	20	MG	PO	MOTIVATION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
CLARITHROMYCIN	500	MG	PO	COMMON COLD	J01FA	MACROLIDES	ANTIBACTERIALS FOR SYSTEMIC USE
CLINDAMYCIN	600	MG	PO	DENTAL INFECTION	J01FF	LINCOSAMIDES	ANTIBACTERIALS FOR SYSTEMIC USE
CLOTRIMAZOL	200	MG	TP	FUNGAL SKIN INFECTION	D01AC	IMIDAZOLE AND TRIAZOLE DERIVATIVES	ANTIFUNGALS FOR DERMATOLOGICAL USE
CLOTRIMAZOL (LOTRICOMB)	010	MG	TP	INGUINAL INTERTRIGO	D01AC	IMIDAZOLE AND TRIAZOLE DERIVATIVES	ANTIFUNGALS FOR DERMATOLOGICAL USE

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
COLECALIFEROL	0010	MCG	PO	OSTEOPOROSIS	A11CC	VITAMIN D AND ANALOGUES	VITAMINS
COTRIM FORTE	0960	MG	PO	URINARY TRACT INFECTION	J01EE	COMB.SULFONAMIDES & TRIMETHOPRIM INCL. DERIVATIVES	ANTIBACTERIALS FOR SYSTEMIC USE
COTRIM FORTE	960	MG	PO	URINARY TRACT INFECTION	J01EE	COMB.SULFONAMIDES & TRIMETHOPRIM INCL. DERIVATIVES	ANTIBACTERIALS FOR SYSTEMIC USE
CRANBEROLA	1	CAP	PO	BLADDER PROPHYLAXIS	G01AD	ORGANIC ACIDS	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS
CYMBALTA	60	MG	PO	AD	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
CYMBALTA	60	MG	PO	PROPHYLAXIS OF DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
DEKRISTOL	400	IU	PO	OSTEOPOROSIS	A11CC	VITAMIN D AND ANALOGUES	VITAMINS
DEXA-CT	0008	MG	IM	PAIN IN SHOULDER	H02AB	GLUCOCORTICOIDS	CORTICOSTEROIDS FOR SYSTEMIC USE
DEXAPOS (R) AT	1	GTT	TP	MACULA EDEMA	S01BA	CORTICOSTEROIDS, PLAIN	OPHTHALMOLOGICALS
DEXPANTHENOL	UNK	GTT	CONJ. TP	OPEN-ANGLE-GLAUCOMA	S01XA	OTHER OPHTHALMOLOGICALS	OPHTHALMOLOGICALS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
DICLOFENAC	0075	MG	PO	HEADACHE AFTER CFS PUNCTURE	M01AB	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
DICLOFENAC	0075	MG	PO	KNEE PAIN	M01AB	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
DICLOFENAC	0075	MG	IM	LUMBOISCHIALGIA	M01AB	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
DICLOFENAC	0075	MG	PO	PAIN IN LEFT KNEE	M01AB	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
DIMENHYDRINAT	0150	MG	PR	NAUSEA AND EMESIS	N07CA	ANTIVERTIGO PREPARATIONS	OTHER NERVOUS SYSTEM DRUGS
DIMENHYDRINATE / (ARLEVERT)	20	MG	PO	CERVICAL DEGENERATIO	N07CA	ANTIVERTIGO PREPARATIONS	OTHER NERVOUS SYSTEM DRUGS
DITROPAN	5	MG	PO	POLLAKISURIA	G04BD	URINARY ANTISPASMODICS	UROLOGICALS
DONEPEZIL	0005	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	0010	MG	PO	ALZHEIMER DESEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	0010	MG	PO	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	0010	MG	PO	ALZHEIMER'S DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	0010	MG	PO	ALZHEIMER\	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	0010	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	10	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
DONEPEZIL	10	MG	PO	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	10	MG	PO	ALZHEIMERS DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	10	MG	PO	ALZHEIMER\	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	10	MG	PO	ALZHEIMER`S DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	10	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	5	MG	PO	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZIL	5	MG	PO	ALZHEIMERS DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEPEZILE	5	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEZEPIL	0010	MG	PO	ALZHEIMER`S DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DONEZEPIL	5	MG	PO	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
DULOXETIN	20	MG	PO	INCONTINENCE	N06AX	OTHER	PSYCHOANALEPTICS
						ANTIDEPRESSANTS	
DULOXETIN	30	MG	PO	DEPRESSION	N06AX	OTHER	PSYCHOANALEPTICS
						ANTIDEPRESSANTS	
DULOXETIN	60	MG	PO	DEPRESSION	N06AX	OTHER	PSYCHOANALEPTICS
						ANTIDEPRESSANTS	
DULOXETIN	60	MG	PO	MOOD	N06AX	OTHER	PSYCHOANALEPTICS
						ANTIDEPRESSANTS	
ECONAZOL (EPI-PEVARY)	1	%	TP	TINEA PEDIS	D01AC	IMIDAZOLE AND	ANTIFUNGALS FOR
CREME						TRIAZOLE DERIVATIVES	DERMATOLOGICAL USE
ECONAZOL (EPI-PEVARYL	01	%	TP	TINEA PEDIS	D01AC	IMIDAZOLE AND	ANTIFUNGALS FOR
CREME)						TRIAZOLE DERIVATIVES	DERMATOLOGICAL USE
EFFECTIN	150	MG	PO	DEMENTIA ASSOCIATED	N06AX	OTHER	PSYCHOANALEPTICS
				DEPRESSION		ANTIDEPRESSANTS	

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
ENALAPRIL	0010	MG	PO	ARTERIAL HYPERTONIA	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
ENALAPRIL	0020	MG	PO	ARTERIAL HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
ENALAPRIL	5	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
ENALAPRIL RATIOPHARM	10	MG	PO	ART. HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
ENALAPRILMALEAT (CO RENITEC)	20	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
ENOXAPARIN-NATRIUM	7000	I.E.	SC	LEG THROMBOSIS	B01AB	HEPARIN GROUP	ANTITHROMBOTIC AGENTS
ESCITALOPRAM	0020	MG	PO	DEPRESSIVE SYNDROME	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
ESCITALOPRAM	10	MG	PO	AGGRESSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
ETORICOXIB	90	MG	PO	PAIN	M01AH	COXIBS	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
EUNERPAN	0025	MG	PO	NOCTURNAL EXCITATION	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
EUNERPAN	0050	MG	PO	NOCTURNAL EXCITATION	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
EUTHYROX	100	MCG	PO	HYPOTHYROIDISM	H03AA	THYROID HORMONES	THYROID THERAPY
EUTHYROX	100	MCG	PO	THYROID HYPERFUNCTION	H03AA	THYROID HORMONES	THYROID THERAPY
EUTHYROX	75	MCG	PO	HYPOTHYROIDISM	H03AA	THYROID HORMONES	THYROID THERAPY
EXELON	0004.5	MG	PO	ALZHEIMER'S DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON	0004.6	MG	TP	DEMENTIA AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON	0009.5	MG	TP	DEMENTIA AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON	0460	MCG	TP	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON	0950	MCG	TP	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON	9500	MCG	TP	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON	9500	MCG	TP	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON 3 MG	3	MG	PO	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON PATCH	0009.5	MG	TP	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON PFLASTER	0004.6	MG	TP	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
EXELON PFLASTER	0009.5	MG	TP	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
EZETROL	10	MG	PO	HYPERCHOLESTERINEMIA	C01AX	OTHER CARDIAC GLYCOSIDES	CARDIAC THERAPY
FELODIPIN	10	MG	PO	ESSENTIAL HYPERTONUS	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS
FEMIKLIMAN UNO	6500	MCG	PO	POST-MENOPAUSAL COMPLAINTS	V90		UNSPECIFIED HERBAL
FICORTIL AS	1	GTT	TP	MACULA EDEMA	S01BA	CORTICOSTEROIDS, PLAIN	OPHTHALMOLOGICALS
FINASTERID	5	MG	PO	PROSTATEHYPOPLASIA	G04CB	TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	UROLOGICALS
FLU VACCINATION	UNK	UNK	SC	PROPHYLAXIS	J07BB	INFLUENZA VACCINES	VACCINES
FLUVASTATINE	80	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
FOLSAN	05	MG	PO	FOLAT DEFICIENCY	B03BB	FOLIC ACID AND DERIVATIVES	ANTIANEMIC PREPARATIONS
FORADIL	0025	MG	IH	ASTHMA BRONCHALE	R03AC	SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
FORLAX	10	G	PO	OBSTIPATION	A06AD	OSMOTICALLY ACTING LAXATIVES	LAXATIVES
FOSAMAX	70	MG	PO	OSTEOPOROSIS	M05BA	BISPHOSPHONATES	DRUGS FOR TREATMENT OF BONE DISEASES
FRAXIPARIN	0000.3	ML	SC	POST SURGERY SPINAL CANAL STENOSIS	B01AB	HEPARIN GROUP	ANTITHROMBOTIC AGENTS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
GABAPENTIN	100	MG	PO	SCAPULA PAIN	N02BG	OTHER ANALGESICS AND ANTIPYRETICS	ANALGESICS
GABAPENTIN	300	MG	PO	SCAPULA PAIN	N02BG	OTHER ANALGESICS AND ANTIPYRETICS	ANALGESICS
GALAFEM	6500	MCG	PO	HOT FLASH	V90		UNSPECIFIED HERBAL
GALANTAMIN	0008	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GALANTAMIN	0008	MG	PO	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GALANTAMIN	0016	MG	PO	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GALANTAMIN	0024	MG	PO	ALZHEIMER	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GALANTAMIN	16	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GALANTAMIN	24	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GALANTAMINE	16	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GALANTAMINE "REMINYL"	16	MG	PO	ALZHEIMERS DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
GEH-WOHL-FOOTBATH	2000	ML	ID	CRAMP IN THE CALF	V03AX	OTHER THERAPEUTIC PRODUCTS	ALL OTHER THERAPEUTIC PRODUCTS
GLASSES				HYPEROPIA BILATERAL	not codeab		
GLIMEPIRID	1	MG	PO	DIABETES MELLITUS	A10BB	SULFONAMIDES, UREA DERIVATIVES	DRUGS USED IN DIABETES
GLIMEPIRID	3	MG	PO	DIAB. MELLITUS	A10BB	SULFONAMIDES, UREA DERIVATIVES	DRUGS USED IN DIABETES
HALOPERIDOL	0001	MG	PO	INSOMNIA	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
HCT	0012.5	MG	PO	HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
HYDROCHLOROTHIAZID	0012.5	MG	PO	ARTERIAL HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
HYDROCHLOROTHIAZID	0012.5	MG	PO	HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
HYDROCHLOROTHIAZID	0025	MG	PO	HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
HYDROCHLOROTHIAZID	0125	MG	PO	HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
HYDROCHLOROTHIAZID	125	MG	PO	HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
HYDROCHLOROTHIAZID	0012.5	MG	PO	HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
HYDROCHLOROTHIAZID	013	MG	PO	ARTERIAL HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
HYDROCHLOROTHIAZID	25	MG	PO	ARTERIAL HYPERTENSION	C03AA	THIAZIDES, PLAIN	DIURETICS
IBUPROFEN	0400	MG	PO	HEADACHE	M02AA	ANTIINFL. PREP., NON-STERIODS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	0400	MG	PO	LUMBOISCHIALGIA	M02AA	ANTIINFL. PREP., NON-STERIODS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	0400	MG	PO	PAIN IN SHOULDER	M02AA	ANTIINFL. PREP., NON-STERIODS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	0400	MG	PO	PAIN OF THE ACHILLES TENDON, RIGHT SIDE	M02AA	ANTIINFL. PREP., NON-STERIODS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	0600	MG	PO	LUMBOISCHIALGIA	M02AA	ANTIINFL. PREP., NON-STERIODS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
IBUPROFEN	0900	MG	PO	HEADACHE	M02AA	ANTIINFL. PREP., NON-STEROIDS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	400	MG	PO	OSTEOPOROSIS	M02AA	ANTIINFL. PREP., NON-STEROIDS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	600	MG	PO	CHRONICAL PAIN	M02AA	ANTIINFL. PREP., NON-STEROIDS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	600	MG	PO	CHRONICAL PAIN, LUMBOISCHIALGIA	M02AA	ANTIINFL. PREP., NON-STEROIDS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFEN	800	MG	PO	SCAPULA PAIN	M02AA	ANTIINFL. PREP., NON-STEROIDS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
IBUPROFENE	800	MG	PO	CERVICAL DEGENERATIOS	M02AA	ANTIINFL. PREP., NON-STEROIDS FOR TOPICAL USE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
INFLUENZA VACCINE (HEMAGGLUTININ OF INFLUENZA VIRUS)	0015	MCG	IM	INFLUENZA PROPHYLAXIS	J07BB	INFLUENZA VACCINES	VACCINES
INFLUENZA VACCINATION	0,5	ML	IM	INFLUENZA VACCINATION	J07BB	INFLUENZA VACCINES	VACCINES
INKONTAN	30	MG	PO	POLLAKISURIA	G04BD	URINARY ANTISPASMODICS	UROLOGICALS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
INSULIN LISPRO 25% SOLUTE CRYSTALSUSPENSION 75% 1ML : 100 IE	0014	IU	SC	IDDM	A10AD	INSULIN/ANAL.FOR INJ, INTEM.-ACT., COMB .W/FAST ACT.	DRUGS USED IN DIABETES
INSULIN LISPRO 25% SOLUTE CRYSTALSUSPENSION 75% 1ML : 100 IE	0020	IU	SC	IDDM	A10AD	INSULIN/ANAL.FOR INJ, INTEM.-ACT., COMB .W/FAST ACT.	DRUGS USED IN DIABETES
INTRAUTERIN PESSAR				CONTRACEPTION	G02BA	INTRAUTERINE CONTRACEPTIVES	OTHER GYNECOLOGICALS
IRBESARTANE / HCT	150	MG	PO	ART. HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
IS 5 MONO	040	MG	PO	PROPHYLAXIS FOR ANGINA	C01DA	ORGANIC NITRATES	CARDIAC THERAPY
ISDN-RATIOPHARM	0060	MG	PO	ARTERIAL HYPERTENSION	C01DA	ORGANIC NITRATES	CARDIAC THERAPY
JODID	0200	MCG	PO	PROPHYLAXIS	H03CA	IODINE THERAPY	THYROID THERAPY
KALI-ORAL	8	G	PO	POTASSIUM DEFICIENCY	C03DA	ALDOSTERONE ANTAGONISTS	DIURETICS
KREON	01	TBL	PO	PANCREAS ENZYME DEFECT	A09AA	ENZYME PREPARATIONS	DIGESTIVES, INCL. ENZYMES
L-THYROX	75	MCG	PO	HYPOTHYREOSIS	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	0050	MCG	PO	HYPERTHYREOSIS	H03AA	THYROID HORMONES	THYROID THERAPY

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
L-THYROXIN	0075	MCG	PO	HYPOTHYRIOSIS	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	0100	MCG	PO	STRUMECTOMY	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	0100	MCG	PO	SUBSTITUTION AFTER STRUMECTOMY	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	0150	MCG	PO	THYROIDECTOMY	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	100	MCG	PO	HYPOTHYREOSIS	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	25	MG	PO	HYPOTHYREOSIS	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	50	MCG	PO	HYPOTHYREAOSIS	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXIN	75	MCG	PO	HYPOTHYROISM	H03AA	THYROID HORMONES	THYROID THERAPY
L-THYROXINE	75	MCG	PO	HYPOTHYREOSIS	H03AA	THYROID HORMONES	THYROID THERAPY
LANTUS	0015	IU	IM	DIABETES	A10AE	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	DRUGS USED IN DIABETES
LANTUS	20	IU	SC	DIABETES MELLITUS	A10AE	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	DRUGS USED IN DIABETES
LANTUS	40	IU	SC	DIAB. MELL.	A10AE	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	DRUGS USED IN DIABETES
LASIX, FUROSEMID	20	MG	PO	HYPERTENSION	C03CA	SULFONAMIDES, PLAIN	DIURETICS
LERCANIDIPINHYDROCHLOR ID	0010	MG	PO	HYPERTONUS	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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LESCOL MR, FLUVASTATIN	080	MG	PO	HYPERCHOLESTEROLAEMI A	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
LEVETIRACETAM	250	MG	PO	TEMPORAL LOBE EPILEPSY	N03AX	OTHER ANTIEPILEPTICS	ANTIEPILEPTICS
LEVETIRACETAM	500	MG	PO	TEMP. LOBE EPILEPSY	N03AX	OTHER ANTIEPILEPTICS	ANTIEPILEPTICS
LEVOTHYROXIN	100	MCG	PO	HYPOTHYREOSIS	H03AA	THYROID HORMONES	THYROID THERAPY
LINIMENT	2	MG	ID	PAIN IN THE THENAR	D08AX	OTHER ANTISEPTICS AND DISINFECTANTS	ANTISEPTICS AND DISINFECTANTS
LISI-HEXAL	5	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
LOCAL ANAESTHESIA FOR TOOTH EXTRACTION	UNK	UNK	SC	LOKAL ANESTHESIA	N01B		ANESTHETICS
LORAZEPAM	UNK	UNK	PO	AGITATION DUE TO PSYCHOSIS	N05BA	BENZODIAZEPINE DERIVATIVES	PSYCHOLEPTICS
LORAZEPAME	UNK	UNK	PO	WORSENING OF AGGRESSION	N05BA	BENZODIAZEPINE DERIVATIVES	PSYCHOLEPTICS
LOVENOX	80	MG	SC	PELVIC VEIN THROMBOSIS	B01AB	HEPARIN GROUP	ANTITHROMBOTIC AGENTS
LUMIGAN	1- 2	GTT	CONJ. TP	OPEN-ANGLE-GLAUCOMA	S01EE	PROSTAGLANDIN ANALOGUES	OPHTHALMOLOGICALS
LUTAMAX	10	MG	PO	MACULA PROPHYLAXIS	S01XA	OTHER OPHTHALMOLOGICALS	OPHTHALMOLOGICALS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
MACROGOL	0013	G	PO	OBSTIPATION	A06AD	OSMOTICALLY ACTING LAXATIVES	LAXATIVES
MAGNESIUM	0120	MG	PO	CRAMPS OF LEGS	A12CC	MAGNESIUM	MINERAL SUPPLEMENTS
MAGNESIUM VERLA	90	MG	PO	COXARTHROSIS	A12CC	MAGNESIUM	MINERAL SUPPLEMENTS
MAGNETRANS FORTE	0150	MG	PO	FOOD SUPPLEMENT	A02AA	MAGNESIUM COMPOUNDS	DRUGS FOR ACID RELATED DISORDERS
MAGNOSOLV	0006.1	G	PO	CRAMP IN THE CALF	A12CC	MAGNESIUM	MINERAL SUPPLEMENTS
METAMIZOL	500	MG	PO	PAIN	N02BB	PYRAZOLONES	ANALGESICS
MELPERON	1	TBL	PO	SLEEPING DISORDERS	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
MELPERON	12,5	MG	PO	AGITATION / AGGRESSION	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
MELPERON	25	MG	PO	AGITATION + AGGRESSION	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
MELPERON	50	MG	PO	AGITATION + AGGRESSION	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
METAMIZOL	1000	MG	PO	PAIN	N02BB	PYRAZOLONES	ANALGESICS
METAMIZOL	500	MG	PO	CHRONICAL PAIN	N02BB	PYRAZOLONES	ANALGESICS
METAMIZOL	500	MG	PO	PAIN	N02BB	PYRAZOLONES	ANALGESICS
METFORMIN	0500	MG	PO	DIABETES	A10BA	BIGUANIDES	DRUGS USED IN DIABETES
METFORMIN	1000	MG	PO	DIAB. MELL.	A10BA	BIGUANIDES	DRUGS USED IN DIABETES
METFORMIN	1000	MG	PO	DIAB. MELLITUS	A10BA	BIGUANIDES	DRUGS USED IN DIABETES

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
METFORMIN	250	MG	PO	DIABETES MELLITUS	A10BA	BIGUANIDES	DRUGS USED IN DIABETES
METFORMIN	500	MG	PO	DIAB. MELL	A10BA	BIGUANIDES	DRUGS USED IN DIABETES
METO HEXAL RETARD	100	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
METOCLOPRAMID	5	MG	PO	EMESIS	A03FA	PROPULSIVES	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
METOHEXAL	0100	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
METOHEXAL	25	MG	PO	ART. HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
METOPROLOL	0025.5	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
METOPROLOL	25	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
METOPROLOL	47	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
METOPROLOLSUCCINAT	95	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
METROPOLOL	0047.5	MG	PO	HYPERTENSION	C07AB	BETA BLOCKING AGENTS, SELECTIVE	BETA BLOCKING AGENTS
MEXALEN	500	MG	PO	HEADACHE	N02BE	ANILIDES	ANALGESICS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
MICARDIS	40	MG	PO	ART. HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
MIRTAZAPIN	0015	MG	PO	DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
MIRTAZAPIN	0015	MG	PO	INSOMNIA	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
MIRTAZAPIN	0030	MG	PO	DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
MIRTAZAPIN	0045	MG	PO	DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
MIRTAZAPIN	7500	MCG	PO	INSOMNIA	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
MIRTAZAPINE	0015	MG	PO	DEPRESSIVE SYNDROME	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
MIRTAZAPINE	0030	MG	PO	DEPRESSIVE SYNDROME	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
MOLSIBETA	8	MG	PO	PROPHYLAXIS FOR ANGINA P.	C01DX	OTHER VASODILATORS USED IN CARDIAC DISEASES	CARDIAC THERAPY
MOTILIMUM (DOMPERIDON)	0010	MG	PO	EMESIS	A03FA	PROPULSIVES	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
MOVICOL MACROGOL 3350	0013	G	PO	OBSTIPATION	A06AD	OSMOTICALLY ACTING LAXATIVES	LAXATIVES
MUCOBENE	600	MG	PO	PNEUMONIA	R05CB	MUCOLYTICS	COUGH AND COLD PREPARATIONS
NALOXON	0004	MG	PO	SPINAL CANAL STENOSIS	N07BC	DRUGS USED IN OPIOID DEPENDENCE	OTHER NERVOUS SYSTEM DRUGS
NALOXON	16	MG	PO	CHRONICAL PAIN	N07BC	DRUGS USED IN OPIOID DEPENDENCE	OTHER NERVOUS SYSTEM DRUGS
NAPROXEN	250	MG	PO	SCAPULA PAIN	M01AE	PROPIONIC ACID DERIVATIVES	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
NEUROBION	100	MG	PO	B12 DEFICIENCY	A11DB	VIT B1 IN COMB WITH VITAMIN B6 AND/OR VITAMIN B12	VITAMINS
NEUROBION	100	MG	PO	VIT B12 DEFICIENCY	A11DB	VIT B1 IN COMB WITH VITAMIN B6 AND/OR VITAMIN B12	VITAMINS
NEUROTREAT S FORTE	1	TBL	PO	ALCOHOL DEPENDENCY	A11DB	VIT B1 IN COMB WITH VITAMIN B6 AND/OR VITAMIN B12	VITAMINS
NIFEDIPIN	0005	MG	PO	HYPERTENSIVE CRISIS	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS
NILVADIPIN	UNK	UNK	PO	HYPERTENSION	C08CA	DIHYDROPYRIDINE DERIVATIVES	CALCIUM CHANNEL BLOCKERS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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NITROFURANTOIN	50	MG	PO	URINARY TRACT INFECTION	J01XE	NITROFURAN DERIVATIVES	ANTIBACTERIALS FOR SYSTEMIC USE
NOMEXOR	5	MG	PO	HYPERTENSION	N02BB	PYRAZOLONES	ANALGESICS
NOVAMINSULFON	0500	MG	PO	FEVER ANALGESIA	N02BB	PYRAZOLONES	ANALGESICS
NOVAMINSULFON	0500	MG	PO	KNEE PAIN	N02BB	PYRAZOLONES	ANALGESICS
NOVORAPID	0001.5	IU	SC	DIABETES	A10AB	INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	DRUGS USED IN DIABETES
OESTROGENE + MEDROGESTON (PRESOMEN)	0000.3	MG	PO	POSTMENOPAUSAL SYMPTOMS	G03FA	PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
OFLOXIN	100	MG	PO	URINARY TRACT INFECTION	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE
OLEOVIT	8000	IU	PO	VITAMIN D3 DEFICIENCY	A11CC	VITAMIN D AND ANALOGUES	VITAMINS
OLEUM ARACHIDIS	0002	G	TP	FUNGAL SKIN INFECTION	V90		UNSPECIFIED HERBAL
OLMESARTANMEDOXOMIL	40	MG	PO	HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
OLMETEC PLUS	20	MG	PO	HYPERTENSION	C09DA	ANGIOTENSIN II ANTAGONISTS AND DIURETICS	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
OMEPRAZOL	0020	MG	PO	GASTRITIS	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
OMEPRAZOL	0040	MG	PO	GASTRIC PROTECTION	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
OMEPRAZOL	0040	MG	PO	REFLUXOESOPHAGITIS	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
OMEPRAZOL	20	MG	PO	GASTRIC ACID PROTECTION	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
OMERPAZOL	40	MG	PO	GASTRIC CONSERVATION	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
OXAZEPAM	10	MG	PO	INSOMNIA	N05BA	BENZODIAZEPINE DERIVATIVES	PSYCHOLEPTICS
OXYBUTININ	0003.9	MG	TP	POLLAKISURIA	G04BD	URINARY ANTISPASMODICS	UROLOGICALS
OXYBUTYNIN (KENTERA)	0003.9	MG	TP	FREQUENT MICTURITION	G04BD	URINARY ANTISPASMODICS	UROLOGICALS
PANTOLOC	20	MG	PO	GASTRIC PROTECTION	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
PANTOLOC (PANTOPRAZOL)	0020	MG	PO	EMESIS	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS

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PANTOPRAZOL	020	MG	PO	RECURRENT STOMACHE PAIN	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
PANTOPRAZOL	20	MG	PO	CARDIALGIA	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
PANTOPRAZOL	20	MG	PO	GASTRITIS	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
PANTOZOL	20	MG	PO	GASTRIC CONSERVATION	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
PANTOZOL	20	MG	PO	PYROSIS	A02BC	PROTON PUMP INHIBITORS	DRUGS FOR ACID RELATED DISORDERS
PARACETAMOL	0500	MG	PO	FEVER ANALGESIA	N02BE	ANILIDES	ANALGESICS
PARACETAMOL	1	G	IV	HEADACHE	N02BE	ANILIDES	ANALGESICS
PARACETAMOL	500	MG	PO	HEADACHE	N02BE	ANILIDES	ANALGESICS
PARACETAMOL	500	MG	PO	HEADACHE (RECURRENT)	N02BE	ANILIDES	ANALGESICS
PARACETAMOL	500	MG	PO	RINGING IN THE EARS	N02BE	ANILIDES	ANALGESICS
PARACETAMOL	500	MG	PO	SHOULDER + NECK PAIN	N02BE	ANILIDES	ANALGESICS
PARKEMED	500	MG	PO	COMMON COLD	M01AG	FENAMATES	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
PENTOHEXAL	0600	MG	PO	CIRCULATION	C04AD	PURINE DERIVATIVES	PERIPHERAL VASODILATORS
PETROLIUM JELLY	02	G	ID	CRAMP IN THE CALF	D02AC	SOFT PARAFFIN AND FAT PRODUCTS	EMOLLIENTS AND PROTECTIVES
PHENPROCUMON		MG	PO	LEG THROMBOSIS	B01AA	VITAMIN K ANTAGONISTS	ANTITHROMBOTIC AGENTS

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MCG=microgram, ML=milliliter, CAP=capsules, MG=milligram, TBL=tablets, IU=International Units, G=gram, U=units, GTT=drops

Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
PIPAMPERON	100	MG	PO	RESTLESSNESS	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
PIPAMPERON	20	MG	PO	AGITATION DUE TO PSYCHOSIS	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
PIPAMPERON	60	MG	PO	UNREST	N05AD	BUTYROPHENONE DERIVATIVES	PSYCHOLEPTICS
PRAVASTATIN	10	MG	PO	HYPERCHOLESTERINAEMI A	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
PRAVASTATIN	20	MG	PO	HYPERCHOLESTERIN	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
PREDNISOLON	0025	MG	IM	LUMBOISCHIALGIA	H02AB	GLUCOCORTICOIDS	CORTICOSTEROIDS FOR SYSTEMIC USE
PROCAIN 2%	10	ML	IM	SCAPULA PAIN	C05AD	LOCAL ANESTHETICS	VASOPROTECTIVES
PROMETHAZIN	0025	MG	PO	EXITATION	R06AD	PHENOTHIAZINE DERIVATIVES	ANTI HISTAMINES FOR SYSTEMIC USE
PROMETHAZIN	0025	MG	PO	NOCTURNAL EXCITATION	R06AD	PHENOTHIAZINE DERIVATIVES	ANTI HISTAMINES FOR SYSTEMIC USE
PROXEN	500	MG	PO	COMMON COLD	M01AE	PROPIONIC ACID DERIVATIVES	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
PSORIASIS CREME (ASS 4,0, SULFUR 10,0, RICINUS OIL 4,5, ALKALIN COAL. TAR LIQUID 5/0 AD VASELINE 200	UKN	UKN	TP	PSORIASIS	D02AF	SALICYLIC ACID PREPARATIONS	EMOLLIENTS AND PROTECTIVES
QUETIAPIN	0025	MG	PO	DELUSIONAL SYMPTOMS	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
QUETIAPIN	25	MG	PO	MOOD	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
QUETIAPINE	050	MG	PO	ALZHEIMER DISEASE	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
QUETIAPINE	12,5	MG	PO	ALZHEIMER DISEASE	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
QUETIAPINE	25	MG	PO	ALZHEIMER DISEASE	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
RAMIPRIL	0002.5	MG	PO	ART. HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
RAMIPRIL	0002.5	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	0005	MG	PO	ARTERIAL HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	0005	MG	PO	HIGH BLOOD PRESSURE	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	0005	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	0005	MG	PO	HYPERTONUS	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	0010	MG	PO	ARTERIAL HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
RAMIPRIL	05	MG	PO	ARTERIAL HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	10	MG	PO	ARTERIAL HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	10	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	2500	MCG	PO	ARTERIAL HYPERTONIA	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL	5	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
RAMIPRIL COMP 5/25MG	1	TBL	PO	ATR. HYPERTENSION	C09BA	ACE INHIBITORS AND DIURETICS	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
RAMITIDIN	150	MG	PO	HYPERTENSION	C09AA	ACE INHIBITORS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
REBOXETIN	0004	MG	PO	DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
REMINYL	0008	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL	0016	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL	0024	MG	PO	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL	16	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL	24	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL	8	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL	8	MG	PO	ALZHEIMER'S DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL (GALANTAMIN)	16	MG	PO	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL RETARD	0008	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
REMINYL RETARD	16	MG	PO	AD	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
RISPERDAL	0003	MG	PO	ADD-ON	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERDAL QL	1	MG	PO	BEHAVIOURAL DISEASE	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERIDON	0000.5	MG	PO	PSYCHOSIS	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERIDON	0500	MCG	PO	HALLUCINATIONS	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERIDON	1	MG	PO	AGGRESSION	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERIDON	1	MG	PO	BEHAVIOURAL DISORDER	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERIDON	2500	MCG	PO	ALZHEIMERS DISEASE	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERIDONE	1500	MCG	PO	ALZHEIMERS DISEASE	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RISPERIDONE	500	MCG	PO	ALZHEIMER DISEASE	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS

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MCG=microgram, ML=milliliter, CAP=capsules, MG=milligram, TBL=tablets, IU=International Units, G=gram, U=units, GTT=drops

Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
RISPERIDONE	500	MCG	PO	ALZHEIMERS DISEASE	N05AX	OTHER ANTIPSYCHOTICS	PSYCHOLEPTICS
RIVASTIGMIN	0004.6	MG	TRANS -D	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
RIVASTIGMIN	0006	MG	PO	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
RIVASTIGMIN	0009.5	MG	TRANS -ID	ALZHEIMER DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
RIVASTIGMIN	0009.5	MG	ID	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
RIVASTIGMIN (EXELON)	0004.6	MG	TP	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
RIVASTIGMIN (EXELON)	0009.5	MG	TP	ALZHEIMER`S DISEASE	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
RIVASTIGMIN (EXELON) TRANSDERMAL, PATCHES	0009.5	MG	TP	DEMENTIA	N06DA	ANTICHOLINESTERASES	PSYCHOANALEPTICS
ROSUVASTATIN	20	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SCHWEDENBITTER (=SWEDISH BITTERS)	UNK	UNK	PO	FEELING OF COLD	V03AX	OTHER THERAPEUTIC PRODUCTS	ALL OTHER THERAPEUTIC PRODUCTS
SEROPRAM	10	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
SEROPRAM	20	MG	PO	DEPRESSION	N06AB	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	PSYCHOANALEPTICS
SEROQUEL	100	MG	PO	BEHAVIOURAL DISEASE	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
SILYMARIN	86,5	MG	PO	PROPHYLAXIS AGAINST LIVER DAMAGE	V90		UNSPECIFIED HERBAL

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
SIMVASTATIN	0010	MG	PO	HYPERLIPIDAEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	0020	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	0030	MG	PO	HYPERCHOLESTERINAEMI A	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	0030	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	0040	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	0040	MG	PO	HYPERCHOLESTEROLAEMI A	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	10	MG	PO	HYPERLIPIDEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	20	MG	PO	HYPERCHOLESTERIN??MI A	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	20	MG	PO	HYPERCHOLESTERINEAMI A	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	20	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	20	MG	PO	HYPERLIPIDAEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	20	MG	PO	HYPERLIPIDEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
SIMVASTATIN	40	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SIMVASTATIN	80	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SINUPRET FORTE	1	TBL	PO	SINUSITIS	R05X		COUGH AND COLD PREPARATIONS
SORTIS	0020	MG	PO	HYPERCHOLESTERINEMIA	C10AA	HMG COA REDUCTASE INHIBITORS	LIPID MODIFYING AGENTS
SPIRONOLACTON	25	MG	PO	HYPERALDOSTERONISM	C03DA	ALDOSTERONE ANTAGONISTS	DIURETICS
SULTANOL	UNK	UNK	IH	BRONCHOPULMONAL INFECTION	R03AC	SELECTIVE BETA-2-ADRENORECEPTO R AGONISTS	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
TALCID	100	MG	PO	FEELING OF FULLNESS	A02AD	COMB AND COMPL. OF ALUMIN., CALC. AND MAGNES. COMP	DRUGS FOR ACID RELATED DISORDERS
TALCID	500	MG	PO	GASTRITIS + VOMITING	A02AD	COMB AND COMPL. OF ALUMIN., CALC. AND MAGNES. COMP	DRUGS FOR ACID RELATED DISORDERS
TAMSULOSIN	0000.4	MG	PO	PROSTATIC HYPERTROPHIE	G04CA	ALPHA-ADRENORECEPTOR ANTAGONISTS	UROLOGICALS
TAMSULOSINHYDROCHLORID	400	MCG	PO	BPH	G04CA	ALPHA-ADRENORECEPTOR ANTAGONISTS	UROLOGICALS
TAVANIC	1000	MG	PO	PNEUMONIA	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
TAVANIC	500	MG	PO	PNEUMONIA	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE
TAVIPEC	0000.15	G	PO	PNEUMONIA	V90		UNSPECIFIED HERBAL
TAVOR EXPIDET	1	MG	PO	ANXIETY REACTION	N05BA	BENZODIAZEPINE DERIVATIVES	PSYCHOLEPTICS
TEBONIN	120	MG	PO	DEMENTIA	V90		UNSPECIFIED HERBAL
TELFAST	120	MG	PO	ATOPIC DERMATITIS	R06AX	OTHER ANTIHISTAMINES FOR SYSTEMIC USE	ANTIHERISTAMINES FOR SYSTEMIC USE
TEMESTA	0000.5	MG	PO	BEHAVIOURAL DISEASE	N05BA	BENZODIAZEPINE DERIVATIVES	PSYCHOLEPTICS
TERBINAFIN (DERMATIN)	250	MG	PO	TINEA PEDIS	D01BA	ANTIFUNGALS FOR SYSTEMIC USE	ANTIFUNGALS FOR DERMATOLOGICAL USE
THIAMAZOL	10	MG	PO	STRUMA MULTINODUSA, HYPERTHYROIDISM	H03BB	SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	THYROID THERAPY
THROMBO ASS	100	MG	PO	CARDIOVASCULAR	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
THROMBO ASS	100	MG	PO	CARDIOVASCULAR PREVENTION	B01AC	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	ANTITHROMBOTIC AGENTS
THYREX	100	MCG	PO	HYPOTHYROIDISM	H03AA	THYROID HORMONES	THYROID THERAPY

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
THYRONAJOD	75	MCG	PO	STRUMA	H03		THYROID THERAPY
THYROXIN	75	MCG	PO	THYROID INSUFFICIENCY	H03AA	THYROID HORMONES	THYROID THERAPY
TILIDIN	0050	MG	PO	SPINAL CANAL STENOSIS	N02AX	OTHER OPIOIDS	ANALGESICS
TILIDIN	200	MG	PO	CHRONICAL PAIN	N02AX	OTHER OPIOIDS	ANALGESICS
TORASEMID-RATIOPHARM	0005	MG	PO	ARTERIAL HYPERTENSION	C03CA	SULFONAMIDES, PLAIN	DIURETICS
TREVILOR	75	MG	PO	AGGRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
TREVILOR RETARD	0075	MG	PO	DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
TRIAMCINOLON	UNK	UNK	IL	MACULA EDEMA	D07AB	CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
TRIAMCINOLON ACETONID	0010	MG	TP	FUNGAL SKIN INFECTION	D07AB	CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
TRIAMTEREN	0050	MG	PO	HYPERTENSION	C03DB	OTHER POTASSIUM-SPARING AGENTS	DIURETICS
TRICEF (CEFIXIM)	0200	MG	PO	URINARY TRACT INFECTION	J01DB	FIRST-GENERATION CEPHALOSPORINS	ANTIBACTERIALS FOR SYSTEMIC USE

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
TRIPRIM	200	MG	PO	URINARY TRACT INFECTION	J01EE	COMB.SULFONAMIDES & TRIMETHOPRIM INCL. DERIVATIVES	ANTIBACTERIALS FOR SYSTEMIC USE
TRITTICO	100	MG	PO	BEHAVIOURAL DISEASE	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
TRITTICO	50	MG	PO	BEHAVIOURAL DISEASE	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
TRITTICO	50	MG	PO	DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
TROMCARDIN	1	MG	PO	CORONAR HEART DISEASE	C01EX	OTHER CARDIAC COMBINATION PRODUCTS	CARDIAC THERAPY
UNGUETUM EMULSIS	0020	G	TP	FUNGAL SKIN INFECTION	D01AE	OTHER ANTIFUNGALS FOR TOPICAL USE	ANTIFUNGALS FOR DERMATOLOGICAL USE
AQUASUMAC	60	MG	PO	URINARY TRACT INFECTION	G04BD	URINARY ANTISPASMODICS	UROLOGICALS
URIVESC	UNK	ML	IM	VACCINATION	J07BB	INFLUENZA VACCINES	VACCINES
VACCINATION INFLUENZA	0080	MG	PO	ARTERIAL HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
VALSARTAN	80	MG	PO	HYPERTENSION	C09CA	ANGIOTENSIN II ANTAGONISTS, PLAIN	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

NK/UNK/UKN=not known, OAD=once a day, AR=as required, BID=twice a day, TID=three times a day

PO=oral, TP=topical, IV=intravenous, ID=intradermal, IM=intramuscular, SC=subcutaneous

MCG=microgram, ML=milliliter, CAP=capsules, MG=milligram, TBL=tablets, IU=International Units, G=gram, U=units, GTT=drops

Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
VENLAFAXIN	0225	MG	PO	DEPRESSION	N06AX	OTHER ANTIDEPRESSANTS	PSYCHOANALEPTICS
VIT. B12	1	U	IM	DECREASE OF VIT B12	B03BA	VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	ANTIANEMIC PREPARATIONS
VITAMIN B12	0100	MCG	IM	B12 HYPOVITAMINOSIS	B03BA	VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	ANTIANEMIC PREPARATIONS
VITAMIN B12 AND FOLIC ACID	400	MG	PO	HYPERHOMOCYSTEINEMIA	B03BA	VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	ANTIANEMIC PREPARATIONS
VITAMIN E	0100	MG	PO	AD	A11HA	OTHER PLAIN VITAMIN PREPARATIONS	VITAMINS
VITAMINE B12	10	MG	PO	HYPOVITAMINOSIS	B03BA	VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	ANTIANEMIC PREPARATIONS
VITAMINE B12	100	MCG	IM	B12-HYPOVITAMINOSIS	B03BA	VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	ANTIANEMIC PREPARATIONS
VOMEX A	050	MG	PO	PROPHYLAXIS	N07CA	ANTIVERTIGO PREPARATIONS	OTHER NERVOUS SYSTEM DRUGS
XYLONEST 1% + TRIAM	10	MG	IM	SHOULDER PAIN SCAPULA	N01BB	AMIDES	ANESTHETICS
ZOLPIDEM	0010	MG	PO	INSOMNIA	N05CF	BENZODIAZEPINE RELATED DRUGS	PSYCHOLEPTICS

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Listing 16.2.4.4.2: ATC codes and terms WHODRUG (September 01, 2009)

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Medication/therapy	Dose	Unit	Route	Indication	ATC code	ATC Level 4 term	ATC Level 2 Term
ZOLPIDEM	1	TBL	PO	SLEEPING DISORDER	N05CF	BENZODIAZEPINE RELATED DRUGS	PSYCHOLEPTICS
ZOPICLON	7500	MCG	PO	SLEEPING DISORDER	N05CF	BENZODIAZEPINE RELATED DRUGS	PSYCHOLEPTICS
ZOPICLON	UNK	UNK	PO	SLEEP DISORDER	N05CF	BENZODIAZEPINE RELATED DRUGS	PSYCHOLEPTICS
ZOROXIN	400	MG	PO	URINARY TRACT INFECTION	J01MA	FLUOROQUINOLONES	ANTIBACTERIALS FOR SYSTEMIC USE
ZYPREXA	0002.5	MG	PO	BEHAVIOURAL DISEASE	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
ZYPREXA	0005	MG	PO	HALLUCINATIONS	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS
ZYPREXA	0010	MG	PO	HALLUCINATIONS	N05AH	DIAZEPINES, OXAZEPINES AND THIAZEPINES	PSYCHOLEPTICS

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PO=oral, TP=topical, IV=intravenous, ID=intradermal, IM=intramuscular, SC=subcutaneous

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	002	1	SCREENING	-7	16APR2009	10:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH"HTES RISIKO F?R EINE FETTSTOFFWECHSELST"RUNG. APO E3 / E3	< 1:80
							APOEGT		
	004	1	SCREENING	-29	17JUN2009	11:40	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	004	1	SCREENING	-29	17JUN2009	11:40	APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	006	2	SCREENING	-32	25JAN2010	8:45	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH?HTES RISIKO F?R EINE FETTSTOFFWECHSELST?RUNG.	< 1:80
							APOEGT	APO E3 / E3	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	010	1	SCREENING	-26	25JUN2009	9:45	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH"HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	012	1	SCREENING	-32	17JUN2010	12:20	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	012	1	SCREENING	-32	17JUN2010	12:20	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	
							APOEGT		
	014	4	SCREENING	-26	07OCT2009	11:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	< 1:80
							APOEGT		

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	015	4	SCREENING	-32	21JAN2010	10:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	017	5	SCREENING	-22	14JUL2009	10:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	017	5	SCREENING	-22	14JUL2009	10:30	APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	019	5	SCREENING	-21	18NOV2009	13:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	023	4	SCREENING	-19	01JUL2010	11:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	< 1:80
							APOEGT	APO E4 / E4	
	027	20	SCREENING	-21	30SEP2010	10:35	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	027	20	SCREENING	-21	30SEP2010	10:35	APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	030	8	SCREENING	-7	18MAR2010	10:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG.	< 1:80
							APOEGT	APO E3 / E3	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	032	8	SCREENING	-10	08NOV2010	10:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	033	9	SCREENING	-7	28OCT2009	8:15	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	033	9	SCREENING	-7	28OCT2009	8:15	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH?HTES RISIKO F?R EINE FETTSTOFFWECHSELST?RUNG. APO E3 / E3	
							APOEGT		
	042	12	SCREENING	-29	16DEC2009	9:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	043	12	SCREENING	-28	21OCT2009	9:45	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E2 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. PERSONEN MIT DIESEM GENOTYP HABEN EIN ERH?HTES RISIKO F?R EINE MILDE DYSLIPIDMIE.	< 1:80
							APOEGT	APO E2 / E3	
	046	11	SCREENING	-28	14DEC2009	9:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	046	11	SCREENING	-28	14DEC2009	9:30	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	
							APOEGT		
	048	11	SCREENING	-5	17NOV2010	11:10	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	050	21	SCREENING	-51	06SEP2010	14:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	052	21	SCREENING	-52	06SEP2010	14:15	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	052	21	SCREENING	-52	06SEP2010	14:15	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	
							APOEGT		
	055	5	SCREENING	-21	08MAR2010	11:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	< 1:80
							APOEGT	APO E4 / E4	
	057	1	SCREENING	-21	29JUL2010	10:50	HIV TEST	NEGATIVE	NEGATIVE

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	057	1	SCREENING	-21	29JUL2010	10:50	VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80
							APEINT	ES KONNTE DAS ALLEL E2 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. PERSONEN MIT DIESEM GENOTYP HABEN EIN ERHÖHTES RISIKO FÜR EINE MILDE DYSLIPIDMIE.	
							APOEGT	APO E2 / E3	
	066	16	SCREENING	-31	09AUG2010	10:40	HIV TEST	NEGATIVE	NEGATIVE
							VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	066	16	SCREENING	-31	09AUG2010	10:40	APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	067	16	SCREENING	-16	02NOV2010	10:40	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG.	< 1:80
							APOEGT	APO E3 / E3	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	071	18	SCREENING	-20	20OCT2010	10:05	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	080	13	SCREENING	-10	08NOV2010	10:27	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	080	13	SCREENING	-10	08NOV2010	10:27	APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	081	17	SCREENING	-10	04OCT2010	11:20	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	< 1:80
							APOEGT	APO E4 / E4	
	083	17	SCREENING	-15	26OCT2010	11:30	HIV TEST VDRL	NEGATIVE <1:1	NEGATIVE < 1:1

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	083	17	SCREENING	-15	26OCT2010	11:30	TPHA APEINT	1:640 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	087	16	SCREENING	-20	09NOV2010	9:05	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80

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 16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	087	16	SCREENING	-20	09NOV2010	9:05	APOEGT	APO E3 / E4	
	089	5	SCREENING	-28	19OCT2010	12:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	< 1:80
							APOEGT	APO E4 / E4	
	093	17	SCREENING	-3	29NOV2010	12:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
ACI-91	093	17	SCREENING	-3	29NOV2010	12:30	APEINT	ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	
							APOEGT	APO E4 / E4	
	097	12	SCREENING	-21	27OCT2010	8:30	HIV TEST	NEGATIVE	NEGATIVE
							VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80
							APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG.	
							APOEGT	APO E3 / E3	
Placebo	001	1	SCREENING	-7	02APR2009	10:40	HIV TEST	NEGATIVE	NEGATIVE

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	001	1	SCREENING	-7	02APR2009	10:40	VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80
							APEINT	ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	
							APOEGT	APO E4 / E4	
	003	1	SCREENING	-21	07MAY2009	10:10	HIV TEST	NEGATIVE	NEGATIVE
							VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	003	1	SCREENING	-21	07MAY2009	10:10	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH?HTES RISIKO F?R EINE FETTSTOFFWECHSELST?RUNG. APO E3 / E3	
							APOEGT		
	005	2	SCREENING	-16	19MAY2009	14:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH?HTES RISIKO F?R EINE FETTSTOFFWECHSELST?RUNG. APO E3 / E3	< 1:80
							APOEGT		

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	009	1	SCREENING	-33	06AUG2009	11:45	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	011	1	SCREENING	-21	05NOV2009	13:10	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	011	1	SCREENING	-21	05NOV2009	13:10	APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	013	4	SCREENING	-30	17AUG2009	10:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	016	4	SCREENING	-28	01FEB2010	10:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	< 1:80
							APOEGT	APO E4 / E4	
	018	5	SCREENING	-20	03NOV2009	13:15	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	018	5	SCREENING	-20	03NOV2009	13:15	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH?HTES RISIKO F?R EINE FETTSTOFFWECHSELST?RUNG. APO E3 / E3	
							APOEGT		
	020	5	SCREENING	-26	27JAN2010	15:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH?HTES RISIKO F?R EINE FETTSTOFFWECHSELST?RUNG. APO E3 / E3	< 1:80
							APOEGT		

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	024	4	SCREENING	-31	16JUL2010	9:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	< 1:80
							APOEGT	APO E4 / E4	
	028	20	SCREENING	-8	18NOV2010	10:20	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	028	20	SCREENING	-8	18NOV2010	10:20	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	
							APOEGT		
	029	8	SCREENING	-3	26JAN2010	9:45	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	< 1:80
							APOEGT		

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	031	8	SCREENING	-14	06MAY2010	13:15	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	034	9	SCREENING	-22	24FEB2010	8:50	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
 16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	034	9	SCREENING	-22	24FEB2010	8:50	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERH?HTES RISIKO F?R EINE FETTSTOFFWECHSELST?RUNG.	
							APOEGT	APO E3 / E3	
	041	12	SCREENING	-16	23SEP2009	10:30	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	044	12	SCREENING	-28	04NOV2009	9:25	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERH?HTES RISIKO F?R DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	045	11	SCREENING	-14	07DEC2009	9:45	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	045	11	SCREENING	-14	07DEC2009	9:45	APEINT	ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	
							APOEGT	APO E4 / E4	
	047	11	SCREENING	-21	12JUL2010	7:55	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG.	< 1:80
							APOEGT	APO E3 / E3	
	049	21	SCREENING	-51	06SEP2010	10:45	HIV TEST	NEGATIVE	NEGATIVE

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	049	21	SCREENING	-51	06SEP2010	10:45	VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	< 1:80
							APOEGT		
	051	21	SCREENING	-52	06SEP2010	12:40	HIV TEST	NEGATIVE	NEGATIVE
							VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	051	21	SCREENING	-52	06SEP2010	12:40	APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	056	5	SCREENING	-21	31MAR2010	10:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ALLELE E4 IN HOMOZYGOUS FORM WAS DETECTED. THIS MEANS A HIGHER RISK FOR M. ALZHEIMER.	< 1:80
							APOEGT	APO E4 / E4	
	058	1	SCREENING	-21	06DEC2010	10:00	HIV TEST	NEGATIVE	NEGATIVE

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	058	1	SCREENING	-21	06DEC2010	10:00	VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80
							APEINT	ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	
							APOEGT	APO E3 / E4	
	059	1	SCREENING	-2	27DEC2010	13:00	HIV TEST	NEGATIVE	NEGATIVE
							VDRL	<1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	< 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	059	1	SCREENING	-2	27DEC2010	13:00	APEINT	ES KONNTE DAS ALLEL E2 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. PERSONEN MIT DIESEM GENOTYP HABEN EIN ERHÖHTES RISIKO FÜR EINE MILDE DYSLIPIDMIE. APO E2 / E3	
							APOEGT		
	065	16	SCREENING	-20	10AUG2010	11:20	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG. APO E3 / E3	< 1:80
							APOEGT		

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	068	16	SCREENING	-27	26OCT2010	8:55	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E2 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. PERSONEN MIT DIESEM GENOTYP HABEN EIN ERHÖHTES RISIKO FÜR EINE MILDE DYSLIPIDMIE. APO E2 / E3	< 1:80
							APOEGT		
	069	23	SCREENING	-13	24NOV2010	9:42	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	069	23	SCREENING	-13	24NOV2010	9:42	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG.	
							APOEGT	APO E3 / E3	
	072	18	SCREENING	-20	01DEC2010	11:10	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	079	13	SCREENING	-18	19JUL2010	15:00	HIV TEST VDRL	NEGATIVE <1:1 SEROLOGISCH KEIN HINWEIS AUF EINE FRISCHE ODER ABGELAUFENE INFEKTION MIT TREPONEMA PALLIDUM (LUES, SYPHILIS)	NEGATIV < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	082	17	SCREENING	-8	06OCT2010	11:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	082	17	SCREENING	-8	06OCT2010	11:00	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG.	
							APOEGT	APO E3 / E3	
	084	17	SCREENING	-9	08NOV2010	10:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	086	21	SCREENING	-24	04OCT2010	11:05	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA APEINT	<1:80 ES KONNTE DAS ALLEL E4 IN HETEROZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION BEDEUTET EIN LEICHT ERHÖHTES RISIKO FÜR DAS AUFTRETEN EINES M. ALZHEIMER	< 1:80
							APOEGT	APO E3 / E4	
	088	16	SCREENING	-9	30NOV2010	10:00	HIV TEST VDRL	NEGATIVE <1:1 NO SEROLOGICAL EVIDENCE OF AN ACTIVE INFECTION WITH TREPONEMA PALLIDUM, NEITHER IN PATIENTS HISTORY.	NEGATIVE < 1:1
							TPHA	<1:80	< 1:80

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Listing 16.2.4.5: Serology

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Reference range
					Date	Time			
Placebo	088	16	SCREENING	-9	30NOV2010	10:00	APEINT	ES KONNTE DAS ALLEL E3 IN HOMOZYGOTER FORM NACHGEWIESEN WERDEN. DIESE KONSTELLATION GIBT KEINEN HINWEIS AUF EIN ERHÖHTES RISIKO FÜR EINE FETTSTOFFWECHSELSTÖRUNG.	
							APOEGT	APO E3 / E3	

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Listing 16.2.4.6: Inclusion/exclusion criteria

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Inclusion criteria								
						01	02	03	04	05	06	07	08	09
ACI-91	002	1	SCREENING	-7	16APR2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	004	1	SCREENING	-29	17JUN2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	006	2	SCREENING	-32	25JAN2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	010	1	SCREENING	-26	25JUN2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	012	1	SCREENING	-32	17JUN2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	014	4	SCREENING	-26	07OCT2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	015	4	SCREENING	-32	21JAN2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	017	5	SCREENING	-22	14JUL2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	019	5	SCREENING	-21	18NOV2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	023	4	SCREENING	-19	01JUL2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	027	20	SCREENING	-21	30SEP2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	030	8	SCREENING	-7	18MAR2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	032	8	SCREENING	-10	08NOV2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	033	9	SCREENING	-7	28OCT2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	042	12	SCREENING	-29	16DEC2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	043	12	SCREENING	-28	21OCT2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	046	11	SCREENING	-28	14DEC2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	048	11	SCREENING	-5	17NOV2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	050	21	SCREENING	-51	06SEP2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	052	21	SCREENING	-52	06SEP2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	055	5	SCREENING	-21	08MAR2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	057	1	SCREENING	-21	29JUL2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	066	16	SCREENING	-31	09AUG2010	YES	YES	YES	YES	NA	YES	YES	YES	YES

NA=not applicable

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Listing 16.2.4.6: Inclusion/exclusion criteria

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13FEB2013

Treat- ment	Random No.	Exclusion criteria																				
		01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21
ACI-91	002	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	004	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	006	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	010	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	012	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	014	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	015	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	017	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	019	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	023	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	027	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	030	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	032	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	033	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	042	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	043	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	046	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	048	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	050	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	052	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	055	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	057	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	066	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO

NA=not applicable

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Listing 16.2.4.6: Inclusion/exclusion criteria

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Treat- ment	Random No.	Exclusion criteria								All incl. criteria fullfilled	No excl. criteria fullfilled
		22	23	24	25	26	27	28	29		
ACI-91	002	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	004	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	006	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	010	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	012	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	014	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	015	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	017	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	019	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	023	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	027	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	030	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	032	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	033	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	042	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	043	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	046	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	048	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	050	NO	NO	NO	YES	NO	NO	NO	NO	YES	NO
	052	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	055	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	057	NO	NO	NO	NO	NO	NO	NO		YES	YES
	066	NO	NO	NO	NO	NO	NO	NO		YES	NO

NA=not applicable

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.4.6: Inclusion/exclusion criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Inclusion criteria								
						01	02	03	04	05	06	07	08	09
ACI-91	067	16	SCREENING	-16	02NOV2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	071	18	SCREENING	-20	20OCT2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	080	13	SCREENING	-10	08NOV2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	081	17	SCREENING	-10	04OCT2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	083	17	SCREENING	-15	26OCT2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	087	16	SCREENING	-20	09NOV2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	089	5	SCREENING	-28	19OCT2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	093	17	SCREENING	-3	29NOV2010	YES	NO	YES	YES	YES	YES	YES	YES	YES
	097	12	SCREENING	-21	27OCT2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
Placebo	001	1	SCREENING	-7	02APR2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	003	1	SCREENING	-21	07MAY2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	005	2	SCREENING	-16	19MAY2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	009	1	SCREENING	-33	06AUG2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	011	1	SCREENING	-21	05NOV2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	013	4	SCREENING	-30	17AUG2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	016	4	SCREENING	-28	01FEB2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	018	5	SCREENING	-20	03NOV2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	020	5	SCREENING	-26	27JAN2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	024	4	SCREENING	-31	16JUL2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	028	20	SCREENING	-8	18NOV2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	029	8	SCREENING	-3	26JAN2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	031	8	SCREENING	-14	06MAY2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	034	9	SCREENING	-22	24FEB2010	YES	YES	YES	YES	YES	YES	YES	YES	YES

NA=not applicable

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Listing 16.2.4.6: Inclusion/exclusion criteria

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Treat- ment	Random No.	Exclusion criteria																				
		01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21
ACI-91	067	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	071	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	080	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	081	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	083	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	087	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	089	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	093	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	097	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
Placebo	001	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	003	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	005	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	009	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	011	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	013	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	016	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	018	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	020	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	024	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	028	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	029	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	031	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	034	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

NA=not applicable

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.4.6: Inclusion/exclusion criteria

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Treat- ment	Random No.	Exclusion criteria								All incl. criteria fullfilled	No excl. criteria fullfilled
		22	23	24	25	26	27	28	29		
ACI-91	067	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	071	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	080	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	081	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	083	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	087	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	089	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	093	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	097	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
Placebo	001	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	003	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	005	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	009	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	011	NO	NO	NO	NO	YES	NO	NO	NA	YES	NO
	013	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	016	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	018	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	020	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	024	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	028	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	029	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	031	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	034	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO

NA=not applicable

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.4.6: Inclusion/exclusion criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Inclusion criteria								
						01	02	03	04	05	06	07	08	09
Placebo	041	12	SCREENING	-16	23SEP2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	044	12	SCREENING	-28	04NOV2009	YES	YES	YES	YES	YES	YES	YES	YES	YES
	045	11	SCREENING	-14	07DEC2009	YES	YES	YES	YES	NA	YES	YES	YES	YES
	047	11	SCREENING	-21	12JUL2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	049	21	SCREENING	-51	06SEP2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	051	21	SCREENING	-52	06SEP2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	056	5	SCREENING	-21	31MAR2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	058	1	SCREENING	-21	06DEC2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	059	1	SCREENING	-2	27DEC2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	065	16	SCREENING	-20	10AUG2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	068	16	SCREENING	-27	26OCT2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	069	23	SCREENING	-13	24NOV2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	072	18	SCREENING	-20	01DEC2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	079	13	SCREENING	-18	19JUL2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	082	17	SCREENING	-8	06OCT2010	YES	YES	YES	YES	NA	YES	YES	YES	YES
	084	17	SCREENING	-9	08NOV2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	086	21	SCREENING	-24	04OCT2010	YES	YES	YES	YES	YES	YES	YES	YES	YES
	088	16	SCREENING	-9	30NOV2010	YES	YES	YES	YES	YES	YES	YES	YES	YES

NA=not applicable

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Listing 16.2.4.6: Inclusion/exclusion criteria

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Treat- ment	Random No.	Exclusion criteria																				
		01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21
Placebo	041	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	044	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	045	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	047	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	049	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	051	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	056	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	058	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	059	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	065	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	068	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	069	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	072	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	079	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	082	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NA	NO	NO	NO
	084	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	086	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	088	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

NA=not applicable

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.4.6: Inclusion/exclusion criteria

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Treat- ment	Random No.	Exclusion criteria								All incl. criteria fullfilled	No excl. criteria fullfilled
		22	23	24	25	26	27	28	29		
Placebo	041	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	044	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	045	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	047	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	049	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	051	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	056	NO	NO	NO	NO	NO	NO	NO	NA	YES	YES
	058	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	059	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	065	NO	NO	NO	NO	NO	NO	NO		YES	YES
	068	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	069	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	072	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	079	NO	NO	NO	NO	NO	NO	NO	NA	YES	NO
	082	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	084	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
	086	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES
	088	NO	NO	NO	NO	NO	NO	NO	NO	YES	YES

NA=not applicable

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
ACI-91	002	1	V1 (WEEK 0)	1	23APR2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	28	20MAY2009	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	85	16JUL2009	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	169	08OCT2009	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	258	05JAN2010	NO	NO	NO	NO	NO	NO	NO
	004	1	V1 (WEEK 0)	1	16JUL2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	28	12AUG2009	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	92	15OCT2009	YES	NO	NO	NA	NO	NO	NO
	006	2	V1 (WEEK 0)	1	26FEB2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	26MAR2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	21MAY2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	169	13AUG2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	252	04NOV2010	NO	NO	NO	NA	NO	NO	NO
	010	1	V1 (WEEK 0)	1	21JUL2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	31	20AUG2009	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	13OCT2009	NO	NO	NO	NA	NO	NO	NO
	012	1	V1 (WEEK 0)	1	19JUL2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	25	12AUG2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	88	14OCT2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	176	10JAN2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	257	01APR2011	NO	NO	NO	NA	NO	NO	NO
	014	4	V1 (WEEK 0)	1	02NOV2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	32	03DEC2009	NO	NO	NO	NA	NO	NO	NO

NA=not applicable

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Listing 16.2.4.7: Withdrawal criteria

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
ACI-91	014	4	V3 (WEEK 12)	85	25JAN2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	172	22APR2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	256	15JUL2010	NO	NO	NO	NA	NO	NO	NO
	015	4	V1 (WEEK 0)	1	22FEB2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	22MAR2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	85	17MAY2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	162	02AUG2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	248	27OCT2010	NO	NO	NO	NO	NO	NO	NO
	017	5	V1 (WEEK 0)	1	05AUG2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	02SEP2009	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	28OCT2009	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	169	20JAN2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	252	13APR2010	NO	NO	NO	NA	NO	NO	NO
	019	5	V1 (WEEK 0)	1	09DEC2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	06JAN2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	03MAR2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	168	25MAY2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	259	24AUG2010	NO	NO	NO	NA	NO	NO	NO
	023	4	V1 (WEEK 0)	1	20JUL2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	24	12AUG2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	86	13OCT2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	177	12JAN2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	245	21MAR2011	NO	NO	NO	NA	NO	NO	NO

NA=not applicable

1=U München, 2=U Ulm, 4=LMU München, 5=Charite Berlin, 8=U Aachen, 9=Magdeburg, 11=U Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
ACI-91	027	20	V1 (WEEK 0)	1	21OCT2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	18NOV2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	92	20JAN2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	174	12APR2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	259	06JUL2011	NO	NO	NO	NO	NO	NO	NO
	030	8	V1 (WEEK 0)	1	25MAR2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	28	21APR2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	17JUN2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	163	03SEP2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	253	02DEC2010	NO	NO	NO	NA	NO	NO	NO
	032	8	V1 (WEEK 0)	1	18NOV2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	30	17DEC2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	82	07FEB2011	NO	NO	NO	NA	YES	NO	NO
	033	9	V1 (WEEK 0)	1	04NOV2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	02DEC2009	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	78	20JAN2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	169	21APR2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	261	22JUL2010	NO	NO	NO	NO	NO	NO	NO
	042	12	V1 (WEEK 0)	1	14JAN2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	11FEB2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	126	19MAY2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	168	30JUN2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	252	22SEP2010	NO	NO	NO	NO	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
ACI-91	043	12	V1 (WEEK 0)	1	18NOV2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	16DEC2009	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	10FEB2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	176	12MAY2010	NO	NO	NO	NA	NO	NO	NO
	046	11	V1 (WEEK 0)	1	11JAN2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	08FEB2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	87	07APR2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	178	07JUL2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	255	22SEP2010	NO	NO	NO	NO	NO	NO	NO
	048	11	V1 (WEEK 0)	1	22NOV2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	30	21DEC2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	86	15FEB2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	176	16MAY2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	247	26JUL2011	NO	NO	NO	NA	NO	NO	NO
	050	21	V1 (WEEK 0)	1	27OCT2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	22NOV2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	83	17JAN2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	167	11APR2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	251	04JUL2011	NO	NO	NO	NO	NO	NO	NO
	052	21	V1 (WEEK 0)	1	28OCT2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	23NOV2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	82	17JAN2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	166	11APR2011	NO	NO	NO	NO	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
ACI-91	052	21	V5 (WEEK 36)	250	04JUL2011	NO	NO	NO	NO	NO	NO	NO
	055	5	V1 (WEEK 0)	1	29MAR2010	NO	NO	NO	NO	NO	NO	
	057	1	V1 (WEEK 0)	1	19AUG2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	33	20SEP2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	82	08NOV2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	170	04FEB2011	NO	NO	NO	NO	NO	NO	NO
	066	16	V1 (WEEK 0)	1	09SEP2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	28	06OCT2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	83	30NOV2010	NO	NO	NO	NA	NO	NO	NO
	067	16	V1 (WEEK 0)	1	18NOV2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	16DEC2010	NO	NO	NO	NO	NO	NO	NO
	071	18	V1 (WEEK 0)	1	09NOV2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	24	02DEC2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	87	03FEB2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	177	04MAY2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	253	19JUL2011	NO	NO	NO	NA	NO	NO	NO
	080	13	V1 (WEEK 0)	1	18NOV2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	26	13DEC2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	84	09FEB2011	NO	NO	NO	NO	NO	NO	NO
	081	17	V1 (WEEK 0)	1	14OCT2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	33	15NOV2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	89	10JAN2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	175	06APR2011	NO	NO	NO	NA	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
ACI-91	081	17	V5 (WEEK 36)	250	20JUN2011	NO	NO	NO	NA	NO	NO	NO
	083	17	V1 (WEEK 0)	1	10NOV2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	08DEC2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	02FEB2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	168	26APR2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	258	25JUL2011	NO	NO	NO	NA	NO	NO	NO
	087	16	V1 (WEEK 0)	1	29NOV2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	30	28DEC2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	81	17FEB2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	169	16MAY2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	255	10AUG2011	NO	NO	NO	NA	NO	NO	NO
	089	5	V1 (WEEK 0)	1	16NOV2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	14DEC2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	84	07FEB2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	168	02MAY2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	252	25JUL2011	NO	NO	NO	NO	NO	NO	NO
	093	17	V1 (WEEK 0)	1	02DEC2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	35	05JAN2011	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	86	25FEB2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	173	23MAY2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	258	16AUG2011	NO	NO	NO	NA	NO	NO	NO
	097	12	V1 (WEEK 0)	1	17NOV2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	28	14DEC2010	NO	NO	NO	NA	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
ACI-91 Placebo	097 001	12	V3 (WEEK 12)	85	09FEB2011	NO	NO	NO	NA	NO	NO	NO
			V1 (WEEK 0)	1	09APR2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	07MAY2009	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	90	07JUL2009	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	162	17SEP2009	NO	NO	NO	NO	NO	NO	NO
	003	1	V5 (WEEK 36)	246	10DEC2009	NO	NO	NO	NO	NO	NO	NO
			V1 (WEEK 0)	1	28MAY2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	28	24JUN2009	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	90	25AUG2009	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	169	12NOV2009	NO	NO	NO	NO	NO	NO	NO
	005	2	V5 (WEEK 36)	253	04FEB2010	YES	NO	NO	NA	NO	NO	NO
			V1 (WEEK 0)	1	04JUN2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	30JUN2009	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	83	25AUG2009	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	168	18NOV2009	NO	NO	NO	NO	NO	NO	NO
	009	1	V5 (WEEK 36)	258	16FEB2010	NO	NO	NO	NO	NO	NO	NO
			V1 (WEEK 0)	1	08SEP2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	30	07OCT2009	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	94	10DEC2009	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	178	04MAR2010	NO	NO	NO	NO	NO	NO	NO
	011	1	V5 (WEEK 36)	246	11MAY2010	NO	NO	NO	NO	NO	NO	NO
			V1 (WEEK 0)	1	26NOV2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	35	30DEC2009	NO	NO	NO	NO	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
Placebo	011	1	V3 (WEEK 12)	85	18FEB2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	162	06MAY2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	253	05AUG2010	NO	NO	NO	NO	NO	NO	NO
	013	4	V1 (WEEK 0)	1	16SEP2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	14OCT2009	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	85	09DEC2009	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	170	04MAR2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	247	20MAY2010	NO	NO	NO	NO	NO	NO	NO
	016	4	V1 (WEEK 0)	1	01MAR2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	29MAR2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	80	19MAY2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	162	09AUG2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	253	08NOV2010	NO	NO	NO	NA	NO	NO	NO
	018	5	V1 (WEEK 0)	1	23NOV2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	21DEC2009	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	86	16FEB2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	170	11MAY2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	247	27JUL2010	NO	NO	NO	NO	NO	NO	NO
	020	5	V1 (WEEK 0)	1	22FEB2010	NO	NO	NO	NA	NO	NO	
	024	4	V1 (WEEK 0)	1	16AUG2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	31	15SEP2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	87	10NOV2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	171	02FEB2011	NO	NO	NO	NA	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
Placebo	024	4	V5 (WEEK 36)	246	18APR2011	NO	NO	NO	NA	NO	NO	NO
	028	20	V1 (WEEK 0)	1	26NOV2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	26	21DEC2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	89	22FEB2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	180	24MAY2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	273	25AUG2011	NO	NO	NO	NO	NO	NO	NO
	029	8	V1 (WEEK 0)	1	29JAN2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	34	03MAR2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	82	20APR2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	158	05JUL2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	245	30SEP2010	NO	NO	NO	NA	NO	NO	NO
	031	8	V1 (WEEK 0)	1	20MAY2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	27	15JUN2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	90	17AUG2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	174	09NOV2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	251	25JAN2011	NO	NO	NO	NA	NO	NO	NO
	034	9	V1 (WEEK 0)	1	18MAR2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	13APR2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	83	08JUN2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	175	08SEP2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	258	30NOV2010	NO	NO	NO	NA	NO	NO	NO
	041	12	V1 (WEEK 0)	1	09OCT2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	32	09NOV2009	NO	NO	NO	NA	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
Placebo	041	12	V3 (WEEK 12)	89	05JAN2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	167	24MAR2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	251	16JUN2010	NO	NO	NO	NA	NO	NO	NO
	044	12	V1 (WEEK 0)	1	02DEC2009	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	37	07JAN2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	85	24FEB2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	176	26MAY2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	260	18AUG2010	NO	NO	NO	NO	NO	NO	NO
	045	11	V1 (WEEK 0)	1	21DEC2009	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	18JAN2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	15MAR2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	169	07JUN2010	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	260	06SEP2010	NO	NO	NO	NA	NO	NO	NO
	047	11	V1 (WEEK 0)	1	02AUG2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	30AUG2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	80	20OCT2010	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	162	10JAN2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	254	12APR2011	NO	NO	NO	NA	NO	NO	NO
	049	21	V1 (WEEK 0)	1	27OCT2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	22NOV2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	84	18JAN2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	168	12APR2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	252	05JUL2011	NO	NO	NO	NO	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
Placebo	051	21	V1 (WEEK 0)	1	28OCT2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	23NOV2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	97	01FEB2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	167	12APR2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	251	05JUL2011	NO	NO	NO	NO	NO	NO	NO
	056	5	V1 (WEEK 0)	1	21APR2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	19MAY2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	84	13JUL2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	168	05OCT2010	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	259	04JAN2011	NO	NO	NO	NO	NO	NO	NO
	058	1	V1 (WEEK 0)	1	27DEC2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	26	21JAN2011	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	93	29MAR2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	166	10JUN2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	260	12SEP2011	NO	NO	NO	NA	NO	NO	NO
	059	1	V1 (WEEK 0)	1	29DEC2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	24	21JAN2011	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	93	31MAR2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	161	07JUN2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	254	08SEP2011	NO	NO	NO	NA	NO	NO	NO
	065	16	V1 (WEEK 0)	1	30AUG2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	27SEP2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	22NOV2010	NO	NO	NO	NA	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
Placebo	065	16	V4 (WEEK 24)	141	17JAN2011	NO	NO	NO	NA	NO	NO	NO
	068	16	V1 (WEEK 0)	1	22NOV2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	29	20DEC2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	81	10FEB2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	163	03MAY2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	262	10AUG2011	NO	NO	NO	NA	NO	NO	NO
	069	23	V1 (WEEK 0)	1	07DEC2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	37	12JAN2011	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	93	09MAR2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	164	19MAY2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	261	24AUG2011	NO	NO	NO	NA	NO	NO	NO
	072	18	V1 (WEEK 0)	1	21DEC2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	31	20JAN2011	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	85	15MAR2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	169	07JUN2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	262	08SEP2011	NO	NO	NO	NA	NO	NO	NO
	079	13	V1 (WEEK 0)	1	06AUG2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	34	08SEP2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	96	09NOV2010	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	175	27JAN2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	249	11APR2011	NO	NO	NO	NO	NO	NO	NO
	082	17	V1 (WEEK 0)	1	14OCT2010	NO	NO	NO	NA	NO	NO	
			V2 (WEEK 4)	35	17NOV2010	NO	NO	NO	NA	NO	NO	NO

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Listing 16.2.4.7: Withdrawal criteria

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Withdrawal criteria						
						01	02	03	04	05	06	07
Placebo	082	17	V3 (WEEK 12)	84	05JAN2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	175	06APR2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	252	22JUN2011	NO	NO	NO	NA	NO	NO	NO
	084	17	V1 (WEEK 0)	1	17NOV2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	29	15DEC2010	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	84	08FEB2011	NO	NO	NO	NA	NO	NO	NO
			V4 (WEEK 24)	175	10MAY2011	NO	NO	NO	NA	NO	NO	NO
			V5 (WEEK 36)	259	02AUG2011	NO	NO	NO	NA	NO	NO	NO
	086	21	V1 (WEEK 0)	1	28OCT2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	23NOV2010	NO	NO	NO	NO	NO	NO	NO
			V3 (WEEK 12)	83	18JAN2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	167	12APR2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	251	05JUL2011	NO	NO	NO	NO	NO	NO	NO
	088	16	V1 (WEEK 0)	1	09DEC2010	NO	NO	NO	NO	NO	NO	
			V2 (WEEK 4)	27	04JAN2011	NO	NO	NO	NA	NO	NO	NO
			V3 (WEEK 12)	83	01MAR2011	NO	NO	NO	NO	NO	NO	NO
			V4 (WEEK 24)	162	19MAY2011	NO	NO	NO	NO	NO	NO	NO
			V5 (WEEK 36)	264	29AUG2011	NO	NO	NO	NO	NO	NO	NO

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	002	1	SCREENING	-7	16APR2009	YES				
			V1 (WEEK 0)	1	23APR2009		YES		YES	CEREBRAL ATROPHY PARIETAL
			V3 (WEEK 12)	85	16JUL2009		YES		YES	CEREBRAL ATROPHY PARIETAL
			V6 (WEEK 52)	365	22APR2010		NO	21APR2010	YES	CEREBRAL ATROPHY
	004	1	SCREENING	-29	17JUN2009	NO		30JUN2009		
			V1 (WEEK 0)	1	16JUL2009		YES		YES	TEMPORAL CEREBRAL ATROPHY
			V3 (WEEK 12)	92	15OCT2009					FLUID SAMPLING REFUSED, MRI NOT NECESSARY
	006	2	SCREENING	-32	25JAN2010	NO		02FEB2010		
			V1 (WEEK 0)	1	26FEB2010		YES		YES	ATROPHY, ESPECIALLY HIPPOCAMPAL
			V3 (WEEK 12)	85	21MAY2010		YES		YES	ATROPHY, ESPECIALLY HIPPOCAMPAL
			V6 (WEEK 52)	364	24FEB2011		NO	22FEB2011	YES	ATROPHY, LITTLE VASCULAR CHANGES
	010	1	SCREENING	-26	25JUN2009	YES				
			V1 (WEEK 0)	1	21JUL2009		YES		YES	MILD CEREBRAL ATROPHY AND MIKROANGIOPATHY
			V3 (WEEK 12)	85	13OCT2009		NO	08OCT2009	YES	MILD CEREBAL ATROPHY AND MICROANGIOPATHY

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	012	1	SCREENING	-32	17JUN2010	NO		17JUN2010		
			V1 (WEEK 0)	1	19JUL2010		YES		YES	CEREBRAL ATROPHY TEMPORAL AND OF THE HIPPOCAMPUS, MICORANGIOPATHIC CHANGES CEREBRAL ATROPHY TEMPORAL AND OF THE HIPPOCAMPUS, MICROANGIOPATHIC CHANGES CEREBRAL ATROPHY TEMPORAL AND OF THE HIPPOCAMPUS MICROANGIOPATHIE CHANGES
			V3 (WEEK 12)	88	14OCT2010		YES		YES	
			V6 (WEEK 52)	361	14JUL2011		NO	12JUL2011	YES	
	014	4	SCREENING	-26	07OCT2009	YES				
			V1 (WEEK 0)	1	02NOV2009		YES		NO	
			V3 (WEEK 12)	85	25JAN2010		YES		NO	
			V6 (WEEK 52)	361	28OCT2010		NO	28OCT2010	NO	
	015	4	SCREENING	-32	21JAN2010	NO		10FEB2010		
			V1 (WEEK 0)	1	22FEB2010		YES		NO	
			V3 (WEEK 12)	85	17MAY2010		YES		NO	
			V6 (WEEK 52)	365	21FEB2011		NO	21FEB2011	NO	
	017	5	SCREENING	-22	14JUL2009	NO		27JUL2009		
			V1 (WEEK 0)	1	05AUG2009		YES		NO	

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	017	5	V3 (WEEK 12)	85	28OCT2009		YES		NO	
			V6 (WEEK 52)	364	03AUG2010		NO	26JUL2010	NO	
	019	5	SCREENING	-21	18NOV2009	YES				
			V1 (WEEK 0)	1	09DEC2009		NO	25NOV2009	NO	
			V3 (WEEK 12)	85	03MAR2010		YES		NO	
			V6 (WEEK 52)	364	07DEC2010		NO	17DEC2010	NO	
	023	4	SCREENING	-19	01JUL2010	NO		12JUL2010		
			V1 (WEEK 0)	1	20JUL2010		YES		NO	
			V3 (WEEK 12)	86	13OCT2010		YES		NO	
			V6 (WEEK 52)	364	18JUL2011		NO	18JUL2011	NO	
	027	20	SCREENING	-21	30SEP2010	YES				
			V1 (WEEK 0)	1	21OCT2010		YES		NO	
			V6 (WEEK 52)	370	25OCT2011		YES		NO	
	030	8	SCREENING	-7	18MAR2010	YES				
			V1 (WEEK 0)	1	25MAR2010		YES		NO	
			V6 (WEEK 52)	355	14MAR2011		NO	14MAR2011	NO	
	032	8	SCREENING	-10	08NOV2010	YES				

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	032	8	V1 (WEEK 0)	1	18NOV2010		NO	18NOV2010	YES	GLOBAL BRAIN ATHROPHY, MICROANGIOPATHY LESIONS
	033	9	SCREENING	-7	28OCT2009	YES				
			V1 (WEEK 0)	1	04NOV2009		YES		YES	PARIETAL ATROPHY
			V3 (WEEK 12)	78	20JAN2010		YES		YES	PARIETAL ATROPHY
			V6 (WEEK 52)	372	10NOV2010		NO	10NOV2010	NO	
	042	12	SCREENING	-29	16DEC2009	YES				
			V1 (WEEK 0)	1	14JAN2010		YES		NO	
			V3 (WEEK 12)	126	19MAY2010		NO	20MAY2010	NO	
			V6 (WEEK 52)	364	12JAN2011		NO	12JAN2011	NO	
	043	12	SCREENING	-28	21OCT2009	NO		15OCT2009		
			V1 (WEEK 0)	1	18NOV2009		YES		NO	
			V3 (WEEK 12)	85	10FEB2010		NO	10FEB2010	NO	
			V6 (WEEK 52)	267	11AUG2010		YES		NO	
	046	11	SCREENING	-28	14DEC2009	NO		14DEC2009		
			V1 (WEEK 0)	1	11JAN2010		YES		YES	ATROPHY
			V3 (WEEK 12)	87	07APR2010		YES		YES	ATROPHY
			V6 (WEEK 52)	367	12JAN2011		NO	12JAN2011	YES	SMALL HYGROM LEFT FRONTO-TEMPORAL

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	048	11	SCREENING	-5	17NOV2010	NO		17NOV2010		
			V1 (WEEK 0)	1	22NOV2010		YES		YES	TWO SMALL OLD ISCHAMIC LESIONS LEFT SIDE + TEMPORAL ATROPHY TEMPORAL ATROPHY SCLEROSIS OF HYPOCAMPUS BILATERALLY , TWO SMALL ISCHAMIC LESIONS LEFT UNCHANGED AS TO FORMER IMAGING
			V3 (WEEK 12)	86	15FEB2011		YES		YES	
			V6 (WEEK 52)	360	16NOV2011		NO	16NOV2011	YES	
	050	21	SCREENING	-51	06SEP2010	YES				
			V1 (WEEK 0)	1	27OCT2010		YES		NO	
			V6 (WEEK 52)	363	24OCT2011		NO	09NOV2011	NO	
	052	21	SCREENING	-52	06SEP2010	YES				
			V1 (WEEK 0)	1	28OCT2010		YES		NO	
			V6 (WEEK 52)	362	24OCT2011		NO	24OCT2011	NO	
	055	5	SCREENING	-21	08MAR2010	YES				
			V1 (WEEK 0)	1	29MAR2010		YES		NO	
			V6 (WEEK 52)	30	27APR2010		YES		NO	

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	057	1	SCREENING	-21	29JUL2010	NO		29JUL2010		
			V1 (WEEK 0)	1	19AUG2010		YES		YES	MODERATE GLOBAL CEREBRAL ATHROPHY FLAIR HYPERINTENSITY PARIETOOCIPITAL AND PRECENTRAL RIGHT UNSPECIFIC
	066	16	SCREENING	-31	09AUG2010	YES				
			V1 (WEEK 0)	1	09SEP2010		YES		YES	BILAT. ATROPHY OF HIPPOC.
			V3 (WEEK 12)	83	30NOV2010		YES		YES	BILAT. ATROPHY OF HIPPOCARRP.
	067	16	SCREENING	-16	02NOV2010	NO		10NOV2010		
			V1 (WEEK 0)	1	18NOV2010		YES		NO	
	071	18	SCREENING	-20	20OCT2010	NO		28OCT2010		
			V1 (WEEK 0)	1	09NOV2010		YES		NO	
			V6 (WEEK 52)	374	17NOV2011		YES		NO	
	080	13	SCREENING	-10	08NOV2010	NO		15NOV2010		
			V1 (WEEK 0)	1	18NOV2010		YES		NO	
			V3 (WEEK 12)	84	09FEB2011		YES		NO	

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	081	17	SCREENING	-10	04OCT2010	NO		11OCT2010		
			V1 (WEEK 0)	1	14OCT2010		YES		NO	
			V6 (WEEK 52)	376	24OCT2011		YES		NO	
	083	17	SCREENING	-15	26OCT2010	YES				
			V1 (WEEK 0)	1	10NOV2010		YES		NO	
			V6 (WEEK 52)	365	09NOV2011		NO	12OCT2011	NO	
	087	16	SCREENING	-20	09NOV2010	NO		16NOV2010		
			V1 (WEEK 0)	1	29NOV2010		YES		NO	
			V6 (WEEK 52)	365	28NOV2011		YES		NO	
	089	5	SCREENING	-28	19OCT2010	YES				
			V1 (WEEK 0)	1	16NOV2010		YES		NO	
			V3 (WEEK 12)	84	07FEB2011					NOT DONE
			V6 (WEEK 52)	364	14NOV2011		NO	03NOV2011	NO	
	093	17	SCREENING	-3	29NOV2010	YES				
			V1 (WEEK 0)	1	02DEC2010		YES		NO	
			V6 (WEEK 52)	370	06DEC2011		NO			
	097	12	SCREENING	-21	27OCT2010	NO		11NOV2010		
			V1 (WEEK 0)	1	17NOV2010		YES		NO	

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
ACI-91	097	12	V3 (WEEK 12)	85	09FEB2011		YES		NO	
Placebo	001	1	SCREENING	-7	02APR2009	YES				
			V1 (WEEK 0)	1	09APR2009		YES		NO	
			V3 (WEEK 12)	90	07JUL2009		YES		NO	
			V6 (WEEK 52)	365	08APR2010		NO	07APR2010	YES	MILD PROGREDIENT CEREBRAL ATROPHY SINCE 26/03/09
	003	1	SCREENING	-21	07MAY2009	YES				
			V1 (WEEK 0)	1	28MAY2009		YES		NO	
			V3 (WEEK 12)	90	25AUG2009		NO			FLUID SAMPLING REFUSED, MRI NOT NECESSARY
	005	2	SCREENING	-16	19MAY2009	YES				
			V1 (WEEK 0)	1	04JUN2009		YES		NO	
			V3 (WEEK 12)	83	25AUG2009		NO	09SEP2009	NO	
			V6 (WEEK 52)	364	02JUN2010		YES	19MAY2010	NO	
	009	1	SCREENING	-33	06AUG2009	NO		10AUG2009		
			V1 (WEEK 0)	1	08SEP2009		YES		YES	MODERATE GENERALIZED CEREBRAL ATROPHY
			V3 (WEEK 12)	94	10DEC2009		YES		YES	MODERATE GENERALIZED CEREBRAL ATROPHY

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
Placebo	009	1	V6 (WEEK 52)	361	03SEP2010		NO	24AUG2010	YES	MODERATE GENERALIZED CEREBRAL ATROPHY AND HIPPOCAMPUS ATROPHY LEFT + RIGHT
	011	1	SCREENING V1 (WEEK 0)	-21 1	05NOV2009 26NOV2009	NO	YES	05NOV2009	YES	MODERATE GLOBAL CEREBRAL ATROPHY
			V3 (WEEK 12)	85	18FEB2010		YES		YES	MODERATE GLOBAL CEREBRAL ATROPHY
			V6 (WEEK 52)	366	26NOV2010		NO	25NOV2010	YES	MODERATE CEREBRAL ATROPHY, TEMPORAL ACCENTUATED
	013	4	SCREENING V1 (WEEK 0)	-30 1	17AUG2009 16SEP2009	YES	YES		NO	
			V3 (WEEK 12)	85	09DEC2009		YES		NO	
			V6 (WEEK 52)	366	16SEP2010		YES		NO	
	016	4	SCREENING V1 (WEEK 0)	-28 1	01FEB2010 01MAR2010	NO	YES	01MAR2010	NO	
			V3 (WEEK 12)	80	19MAY2010		YES		NO	
			V6 (WEEK 52)	365	28FEB2011		NO	28FEB2011	NO	

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
Placebo	018	5	SCREENING	-20	03NOV2009	NO		16NOV2009		
			V1 (WEEK 0)	1	23NOV2009		YES		NO	
			V3 (WEEK 12)	86	16FEB2010		NO	15FEB2010	NO	
			V6 (WEEK 52)	366	23NOV2010		NO	09DEC2010	NO	
	020	5	SCREENING	-26	27JAN2010	NO		19FEB2010		
			V1 (WEEK 0)	1	22FEB2010		YES		NO	
	024	4	SCREENING	-31	16JUL2010	NO		02AUG2010		
			V1 (WEEK 0)	1	16AUG2010		YES		YES	FRONTAL LESIONS DUE TO TRAUMA WITH INTRA-CEREBRAL BLEEDING AT THE AGE OF 18 SEE VISIT 1 (SAME MRI)
			V3 (WEEK 12)	87	10NOV2010		YES		YES	
			V6 (WEEK 52)	358	08AUG2011		NO	08AUG2011	NO	
	028	20	SCREENING	-8	18NOV2010	YES				
			V1 (WEEK 0)	1	26NOV2010		YES		NO	
			V6 (WEEK 52)	364	24NOV2011		YES		NO	
	029	8	SCREENING	-3	26JAN2010	YES				

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
Placebo	029	8	V1 (WEEK 0)	1	29JAN2010		YES		YES	MARGINAL MICROVASCULAR DISEASE, LIGHT PERISYLVIAN AND PARIETAL REDUCE BRAIN VOLUME
	031	8	SCREENING V1 (WEEK 0)	-14 1	06MAY2010 20MAY2010	NO	YES	06MAY2010	NO	
	034	9	SCREENING V1 (WEEK 0) V3 (WEEK 12) V6 (WEEK 52)	-22 1 83 363	24FEB2010 18MAR2010 08JUN2010 15MAR2011	YES	NO NO NO	 14JUN2010 15MAR2011	NO NO NO	
	041	12	SCREENING V1 (WEEK 0) V3 (WEEK 12) V6 (WEEK 52)	-16 1 89 363	23SEP2009 09OCT2009 05JAN2010 06OCT2010	NO	YES YES NO	24SEP2009 06OCT2010	NO NO NO	
	044	12	SCREENING V1 (WEEK 0) V3 (WEEK 12) V6 (WEEK 52)	-28 1 85 365	04NOV2009 02DEC2009 24FEB2010 01DEC2010	NO	YES YES NO	03NOV2009 	NO NO	

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Listing 16.2.4.8: MRI report

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
Placebo	045	11	SCREENING	-14	07DEC2009	NO		07DEC2009		
			V1 (WEEK 0)	1	21DEC2009		YES		YES	ATROPHY & MICROANGIOPATHY
			V3 (WEEK 12)	85	15MAR2010		YES		YES	ATROPHY
			V6 (WEEK 52)	360	15DEC2010		NO	15DEC2010	YES	MICROANGIOPATHY + ATROPHY
	047	11	SCREENING	-21	12JUL2010	NO		12JUL2010		
			V1 (WEEK 0)	1	02AUG2010		YES		YES	GLOBAL ATROPHY, MINOR LEUKENCEPHALOPATHY
			V3 (WEEK 12)	80	20OCT2010		YES		YES	GLOBAL ATROPHY, MINOR LEUKENCEPHALOPATHY
			V6 (WEEK 52)	360	27JUL2011		NO	27JUL2011	NO	
	049	21	SCREENING	-51	06SEP2010	YES				
			V1 (WEEK 0)	1	27OCT2010		YES		NO	
	051	21	SCREENING	-52	06SEP2010	NO		07SEP2010		
			V1 (WEEK 0)	1	28OCT2010		YES		NO	
			V6 (WEEK 52)	363	25OCT2011		NO	09NOV2011	NO	
	056	5	SCREENING	-21	31MAR2010	NO		13APR2010		
			V1 (WEEK 0)	1	21APR2010		YES		NO	
			V3 (WEEK 12)	84	13JUL2010		YES		NO	
			V6 (WEEK 52)	364	19APR2011		NO	28APR2011	NO	

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Listing 16.2.4.8: MRI report

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
Placebo	058	1	SCREENING	-21	06DEC2010	YES				
			V1 (WEEK 0)	1	27DEC2010		YES		YES	SOME CEREBRALOTROPHY TEMPRORAL ACCENTUATED, SUSPECT OF LITTLE MONODIAL PLEXUS CYST
	059	1	V6 (WEEK 52)	345	06DEC2011		NO	06DEC2011	YES	TEMPORAL ATROPHY
			SCREENING	-2	27DEC2010	YES				
	059	1	V1 (WEEK 0)	1	29DEC2010		NO	18FEB2010	YES	DISCRETE CEREBRAL ATROPHY FRONTAL ACCENTUATED WITH DISCRETE ATROPHY OF THE HIPPOCAMPUS ON BOTH SIDES_ SPORADIC T2 HYPERINTENSE LESIONS
			V6 (WEEK 52)	345	08DEC2011		NO	21NOV2011	YES	ATROPHIE TEMPORAL
	065	16	SCREENING	-20	10AUG2010	NO		17AUG2010		
			V1 (WEEK 0)	1	30AUG2010		YES		NO	
	068	16	V3 (WEEK 12)	85	22NOV2010		YES		NO	
			SCREENING	-27	26OCT2010	NO		02NOV2010		
			V1 (WEEK 0)	1	22NOV2010		YES		NO	
			V3 (WEEK 12)	81	10FEB2011		YES		NO	

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
Placebo	068	16	V6 (WEEK 52)	372	28NOV2011		YES		NO	
	069	23	SCREENING	-13	24NOV2010	YES				
			V1 (WEEK 0)	1	07DEC2010		NO			
			V3 (WEEK 12)	93	09MAR2011		YES		NO	
			V6 (WEEK 52)	373	14DEC2011		YES		NO	
	072	18	SCREENING	-20	01DEC2010	NO		09DEC2010		
			V1 (WEEK 0)	1	21DEC2010		YES		NO	
			V6 (WEEK 52)	360	15DEC2011		YES		NO	
	079	13	SCREENING	-18	19JUL2010	YES				
			V1 (WEEK 0)	1	06AUG2010		NO	12AUG2010	NO	
			V3 (WEEK 12)	96	09NOV2010		YES		NO	
			V6 (WEEK 52)	320	21JUN2011		YES		NO	
	082	17	SCREENING	-8	06OCT2010	YES				
			V1 (WEEK 0)	1	14OCT2010		YES		NO	
			V3 (WEEK 12)	84	05JAN2011		NO			
			V6 (WEEK 52)	364	12OCT2011		NO	20SEP2011	NO	
	084	17	SCREENING	-9	08NOV2010	YES				
			V1 (WEEK 0)	1	17NOV2010		YES		NO	

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Listing 16.2.4.8: MRI report

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Report avail- able*	Report avail- able**	MRI date	Clin.Sign. finding	Finding
Placebo	084	17	V3 (WEEK 12)	84	08FEB2011		NO			
			V6 (WEEK 52)	371	22NOV2011		NO	30AUG2011	NO	
	086	21	SCREENING	-24	04OCT2010	YES				
			V1 (WEEK 0)	1	28OCT2010		YES		NO	
			V6 (WEEK 52)	363	25OCT2011		NO	02NOV2011	NO	
	088	16	SCREENING	-9	30NOV2010	NO		02DEC2010		
			V1 (WEEK 0)	1	09DEC2010		YES		NO	
			V3 (WEEK 12)	83	01MAR2011		YES		NO	
			V6 (WEEK 52)	376	19DEC2011		YES		NO	

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Listing 16.2.4.9: Randomization details

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13FEB2013

Site ID	Random No.	Treatment randomized/ actual received
1	001	Placebo
	002	ACI-91
	003	Placebo
	004	ACI-91
	009	Placebo
	010	ACI-91
	011	Placebo
	012	ACI-91
	057	ACI-91
	058	Placebo
	059	Placebo
2	005	Placebo
	006	ACI-91
4	013	Placebo
	014	ACI-91
	015	ACI-91
	016	Placebo
	023	ACI-91
	024	Placebo
5	017	ACI-91
	018	Placebo

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Listing 16.2.4.9: Randomization details

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Site ID	Random No.	Treatment randomized/ actual received
5	019	ACI-91
	020	Placebo
	055	ACI-91
	056	Placebo
	089	ACI-91
8	029	Placebo
	030	ACI-91
	031	Placebo
	032	ACI-91
9	033	ACI-91
	034	Placebo
11	045	Placebo
	046	ACI-91
	047	Placebo
	048	ACI-91
12	041	Placebo
	042	ACI-91
	043	ACI-91
	044	Placebo
	097	ACI-91

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Listing 16.2.4.9: Randomization details

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Site ID	Random No.	Treatment randomized/ actual received
13	079	Placebo
	080	ACI-91
16	065	Placebo
	066	ACI-91
	067	ACI-91
	068	Placebo
	087	ACI-91
	088	Placebo
17	081	ACI-91
	082	Placebo
	083	ACI-91
	084	Placebo
	093	ACI-91
18	071	ACI-91
	072	Placebo
20	027	ACI-91
	028	Placebo
21	049	Placebo
	050	ACI-91

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Listing 16.2.4.9: Randomization details

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Site ID	Random No.	Treatment randomized/ actual received
21	051	Placebo
	052	ACI-91
	086	Placebo
23	069	Placebo

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Listing 16.2.5.1: Drug compliance

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13FEB2013

Treat- ment	Random No.	Site ID	Sum of tablets dispensed	Sum of tablets returned	Sum of tablets used	Compliance [%]	Day of week 52 (day 364)	Compliant
ACI-91	002	1	910	189	721	98.77	365	YES
	004	1	210	15	195			NO
	006	2	910	196	714	98.08	364	YES
	010	1	420	46	374			NO
	012	1	910	290	620	85.87	361	YES
	014	4	910	194	716	99.17	361	YES
	015	4	910	181	729	99.86	365	YES
	017	5	910	189	721	99.04	364	YES
	019	5	910	198	712	97.80	364	YES
	023	4	910	185	725	99.59	364	YES
	027	20	940	206	734	99.19	370	YES
	030	8	910	205	705	99.30	355	YES
	032	8	210	44	166			NO
	033	9	700	136	564	75.81	372	NO
	042	12	910	218	692	95.05	364	YES
	043	12	630	124	506	94.76	267	YES
	046	11	910	179	731	99.59	367	YES
	048	11	910	193	717	99.58	360	YES
	050	21	910	135	775	106.75	363	YES
	052	21	910	232	678	93.65	362	YES
	055	5	70	69	1	1.67	30	NO
	057	1	420	129	291			NO
	066	16	420	56	364			NO

Data based on tablets dispensed/returned

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Listing 16.2.5.1: Drug compliance

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13FEB2013

Treat- ment	Random No.	Site ID	Sum of tablets dispensed	Sum of tablets returned	Sum of tablets used	Compliance [%]	Day of week 52 (day 364)	Compliant
ACI-91	067	16	210	146	64	46.38	69	NO
	071	18	910	165	745	99.60	374	YES
	080	13	420	210	210	53.57	196	NO
	081	17	910	164	746	99.20	376	YES
	083	17	910	174	736	100.82	365	YES
	087	16	910	189	721	98.77	365	YES
	089	5	910	185	725	99.59	364	YES
	093	17	910	163	747	100.95	370	YES
	097	12	420	47	373			NO
	001	1	700	129	571	78.22	365	NO
Placebo	003	1	630	126	504			NO
	005	2	910	135	775	106.46	364	YES
	009	1	910	191	719	99.58	361	YES
	011	1	910	180	730	99.73	366	YES
	013	4	910	187	723	98.77	366	YES
	016	4	910	172	738	101.10	365	YES
	018	5	910	174	736	100.55	366	YES
	020	5	70					NO
	024	4	910	200	710	99.16	358	YES
	028	20	910	210	700	96.15	364	YES
	029	8	910	177	733	99.32	369	YES
	031	8	910	195	715	98.48	363	YES
	034	9	980	169	811	111.71	363	YES

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Listing 16.2.5.1: Drug compliance

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13FEB2013

Treat- ment	Random No.	Site ID	Sum of tablets dispensed	Sum of tablets returned	Sum of tablets used	Compliance [%]	Day of week 52 (day 364)	Compliant
Placebo	041	12	910	169	741	102.07	363	YES
	044	12	910	573	337	46.16	365	NO
	045	11	910	219	691	95.97	360	YES
	047	11	910	192	718	99.72	360	YES
	049	21	910	133	777			NO
	051	21	910	186	724	99.72	363	YES
	056	5	910	194	716	98.35	364	YES
	058	1	910	385	525	76.09	345	NO
	059	1	910	234	676	97.97	345	YES
	065	16	630	140	490			NO
	068	16	910	176	734	98.66	372	YES
	069	23	910	167	743	99.60	373	YES
	072	18	910	267	643	89.31	360	YES
	079	13	910	294	616	96.25	320	YES
	082	17	910	202	708	97.25	364	YES
	084	17	910	170	740	99.73	371	YES
	086	21	910	219	691	95.18	363	YES
	088	16	910	166	744	98.94	376	YES

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
ACI-91	002	1	V1 (WEEK 0)	1	2009-04-23	8:55	ND	2009-04-23	11:00	<LLOQ	
			V3 (WEEK 12)	85	2009-07-16	8:30	83.4	2009-07-16	10:45	9.41	
			V6 (WEEK 52)	365	2010-04-22	10:10	157	2010-04-22	12:00	8.72	
	004	1	V1 (WEEK 0)	1	2009-07-16	10:00	ND	2009-07-16	11:45	<LLOQ	
			V3 (WEEK 12)	92	2009-10-15	14:50	46.3			NS	REFUSED (SEE COMMENT)
	006	2	V1 (WEEK 0)	1	2010-02-26	9:00	0.547	2010-02-26	10:00	<LLOQ	
			V3 (WEEK 12)	85	2010-05-21	9:15	113	2010-05-21	10:00	13.5	
			V6 (WEEK 52)	364	2011-02-24	8:20	65.9	2011-02-24	9:00	11.4	
	010	1	V1 (WEEK 0)	1	2009-07-21	11:00	ND	2009-07-21	12:30	<LLOQ	
			V3 (WEEK 12)	85	2009-10-13	10:45	193	2009-10-13	11:25	18.2	
	012	1	V1 (WEEK 0)	1	2010-07-19	10:00	ND	2010-07-19	11:10	ND	
			V3 (WEEK 12)	88	2010-10-14	9:15	55.5			NS	PATIENT REFUSED FLUID SAMPLING
			V6 (WEEK 52)	361	2011-07-14	10:25	128	2011-07-14	11:00	18.3	
	014	4	V1 (WEEK 0)	1	2009-11-02	9:30	ND	2009-11-02	12:30	<LLOQ	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
ACI-91	014	4	V3 (WEEK 12)	85	2010-01-25	10:00	50.0			NS	PATIENT RESFUSED TO BE LUMBAR PUNCTURED
			V6 (WEEK 52)	361	2010-10-28	11:00	87.6	2010-10-28	11:50	11.8	
	015	4	V1 (WEEK 0)	1	2010-02-22	9:00	ND	2010-02-22	11:30	<LLOQ	PATIENT REFUSED PUNCTURE
			V3 (WEEK 12)	85	2010-05-17	10:00	167			NS	
			V6 (WEEK 52)	365	2011-02-21	10:30	150	2011-02-21	12:00	17.5	
	017	5	V1 (WEEK 0)	1	2009-08-05	9:00	ND	2009-08-05	13:25	<LLOQ	
			V3 (WEEK 12)	85	2009-10-28	8:45	92.0	2009-10-28	13:30	5.82	
			V6 (WEEK 52)	364	2010-08-03	9:00	126	2010-08-03	11:00	11.8	
	019	5	V1 (WEEK 0)	1	2009-12-09	9:00	ND	2009-12-09	13:30	0.329	
			V3 (WEEK 12)	85	2010-03-03	9:00	184	2010-03-03	13:15	19.4	
			V6 (WEEK 52)	364	2010-12-07	13:30	189	2010-12-07	13:30	20.7	
	023	4	V1 (WEEK 0)	1	2010-07-20	10:00	ND	2010-07-20	12:00	<LLOQ	PATIENT REFUSED TO BE LUMBARPUNCTURED
			V3 (WEEK 12)	86	2010-10-13	9:30	136			NS	
			V6 (WEEK 52)	364	2011-07-18	10:00	31.4	2011-07-18	12:45	6.00	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
ACI-91	027	20	V1 (WEEK 0)	1	2010-10-21	9:15	ND	2010-10-21	12:30	ND	OPTIONAL, PATIENT DOES NOT WANT
			V3 (WEEK 12)	92	2011-01-20	10:55	49.7			NS	
			V6 (WEEK 52)	370	2011-10-25	8:19	52.7	2011-10-25	13:45	2.95	
	030	8	V1 (WEEK 0)	1	2010-03-25	10:20	313	2010-03-25	12:45	0.528	OPTIONAL
			V3 (WEEK 12)	85	2010-06-17	11:50	150			NS	
			V6 (WEEK 52)	355	2011-03-14	11:00	116	2011-03-14	14:15	19.3	
	032	8	V1 (WEEK 0)	1	2010-11-18	10:10	ND	2010-11-18	14:00	ND	OPTIONAL !
			V3 (WEEK 12)	82	2011-02-07	12:23	115			NS	
	033	9	V1 (WEEK 0)	1	2009-11-04	8:00	ND	2009-11-04	11:20	0.429	PATIENT REFUSED
			V3 (WEEK 12)	78	2010-01-20	9:05	224			NS	
			V6 (WEEK 52)	372	2010-11-10	8:30	229	2010-11-10	12:40	15.4	
	042	12	V1 (WEEK 0)	1	2010-01-14	9:15	ND	2010-01-20	10:30	13.8	NOT ACCEPTED BY PATIENT PUNCTURE FAILED
			V3 (WEEK 12)	126	2010-05-19	8:30	167			NS	
			V6 (WEEK 52)	364	2011-01-12	8:30	38.5			NS	
	043	12	V1 (WEEK 0)	1	2009-11-18	9:30	ND	2009-11-18	14:00	<LLOQ	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
ACI-91	043	12	V3 (WEEK 12)	85	2010-02-10	9:30	148			NS	NOT ACCEPTED BY PATIENT TOO BAD GENERAL CONDITION
			V6 (WEEK 52)	267							
	046	11	V1 (WEEK 0)	1	2010-01-11	9:45	ND	2010-01-11	13:30	0.350	PAT. DENIED
			V3 (WEEK 12)	87							
			V6 (WEEK 52)	367		2011-01-12	8:00	172	2011-01-12	13:30	
	048	11	V1 (WEEK 0)	1	2010-11-22	10:30	ND	2010-11-22	12:30	ND	PAT. DENIED
			V3 (WEEK 12)	86							
			V6 (WEEK 52)	360		2011-11-16	10:00	135	2011-11-16	13:00	
	050	21	V1 (WEEK 0)	1	2010-10-27	11:45	ND	2010-10-27	14:00	<LLOQ	PATIENT REFUSED OPTIONAL LUMBAR PUNCTURE
			V3 (WEEK 12)	83							
			V6 (WEEK 52)	363		2011-10-24	9:00		214	2011-10-24	
	052	21	V1 (WEEK 0)	1	2010-10-28	8:15	ND	2010-10-28	11:15	ND	PATIENT REFUSED OPTIONAL LUMBAR PUNCTURE
			V3 (WEEK 12)	82							
			V6 (WEEK 52)	362		2011-10-24	12:15	88.7	2011-10-24	14:55	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
ACI-91	055	5	V1 (WEEK 0)	1	2010-03-29	9:30	ND	2010-03-29	13:15	<LLOQ NS	EARLY TERMINATION
			V6 (WEEK 52)	30	2010-04-27	9:15	ND				
	057	1	V1 (WEEK 0)	1	2010-08-19	11:10	ND	2010-08-19	13:40	ND NS	PATIENT REFUSED
			V3 (WEEK 12)	82	2010-11-08	9:45	140				
	066	16	V1 (WEEK 0)	1	2010-09-09	9:25	ND	2010-09-09	8:45	ND NS	PATIENT DONT GIVEN CONSENT, BECAUSE SAMPLING IS OPTIONAL
			V3 (WEEK 12)	83	2010-11-30	9:15	113				
	067	16	V1 (WEEK 0)	1	2010-11-18	8:30	ND	2010-11-18	8:15	ND NS	EARLY TERMINATION
			V6 (WEEK 52)	69	2011-01-25	10:50	ND				
	071	18	V1 (WEEK 0)	1	2010-11-09	11:00	ND	2010-11-09	15:05	ND NS	CAREGIVER AND PATIENT DID NOT WANT TO
			V3 (WEEK 12)	87	2011-02-03	10:07	148				
			V6 (WEEK 52)	374	2011-11-17	11:02	120	2011-11-24	11:10	NS	
	080	13	V1 (WEEK 0)	1	2010-11-18	12:30	ND	2010-11-19	14:00	ND	
			V3 (WEEK 12)	84	2011-02-09	11:30	104	2011-02-09	13:40	17.3	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
ACI-91	080	13	V6 (WEEK 52)	196							NOT PERFORMED DUE TO SAE
	081	17	V1 (WEEK 0)	1	2010-10-14	10:00	ND	2010-10-14	13:30	ND	
			V3 (WEEK 12)	89							OPTIONAL
			V6 (WEEK 52)	376							BECAUSE OF HEMORRHAGE
	083	17	V1 (WEEK 0)	1	2010-11-10	9:25	ND	2010-11-10	13:30	ND	
			V3 (WEEK 12)	85							THIS TEST IS OPTIONAL
			V6 (WEEK 52)	365	2011-11-09	10:20	ND	2011-11-10	9:30	ND	
	087	16	V1 (WEEK 0)	1	2010-11-29	10:10	ND	2010-11-29	9:45	ND	
			V3 (WEEK 12)	81	2011-02-17	9:35	186			NS	PATIENT DONT GIVEN CONSENT FOR OPTIONAL CF-SAMPLING
			V6 (WEEK 52)	365	2011-11-28	10:15	181	2011-11-28	9:45	27.3	
	089	5	V1 (WEEK 0)	1	2010-11-16	12:00	ND	2010-11-16	12:00	ND	
			V3 (WEEK 12)	84	2011-02-07	11:30	102			NS	PATIENT WAS TOO AGITATED
			V6 (WEEK 52)	364							PATIENT TOO AGITATED
	093	17	V1 (WEEK 0)	1	2010-12-02	8:30	ND	2010-12-02	13:30	ND	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
ACI-91	093	17	V3 (WEEK 12) V6 (WEEK 52)	86 370							OPTIONAL PATIENT REFUSED
	097	12	V1 (WEEK 0) V3 (WEEK 12)	1 85	2010-11-17 2011-02-09	8:30 8:15	ND 125	2010-11-17	12:00	ND NS	NOT ACCEPTED BY PATIENT
Placebo	001	1	V1 (WEEK 0) V3 (WEEK 12) V6 (WEEK 52)	1 90 365	2009-04-09 2009-07-07 2010-04-08	10:30 8:55 9:00	ND ND ND	2009-04-09 2009-07-07 2010-04-08	11:15 12:05 11:30	<LLOQ <LLOQ <LLOQ	
	003	1	V1 (WEEK 0) V3 (WEEK 12)	1 90	2009-05-28	11:25	ND	2009-05-28	10:00	<LLOQ	REFUSED
	005	2	V1 (WEEK 0) V3 (WEEK 12) V6 (WEEK 52)	1 83 364	2009-06-04 2009-08-25 2010-06-02	8:45 8:30 9:00	ND ND ND	2009-06-04 2009-08-25 2010-06-02	11:00 11:00 10:30	<LLOQ <LLOQ ND	
	009	1	V1 (WEEK 0) V3 (WEEK 12) V6 (WEEK 52)	1 94 361	2009-09-08 2009-12-10 2010-09-03	9:10 9:40 10:15	ND ND ND	2009-09-08 2009-12-10 2010-09-03	11:30 11:50 13:20	<LLOQ <LLOQ ND	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
Placebo	011	1	V1 (WEEK 0)	1	2009-11-26	10:25	ND	2009-11-26	11:10	<LLOQ	
			V3 (WEEK 12)	85	2010-02-18	9:05	ND	2010-02-18	11:10	<LLOQ	
			V6 (WEEK 52)	366	2010-11-26	10:10	ND	2010-11-26	11:10	ND	
	013	4	V1 (WEEK 0)	1	2009-09-16	9:00	ND	2009-09-16	12:30	<LLOQ	
			V3 (WEEK 12)	85	2009-12-09	10:00	ND	2009-12-09	13:00	<LLOQ	
			V6 (WEEK 52)	366	2010-09-16	11:00	ND	2010-09-16	13:00	ND	
	016	4	V1 (WEEK 0)	1	2010-03-01	10:00	ND	2010-03-01	12:00	<LLOQ	
			V3 (WEEK 12)	80	2010-05-19	9:15	ND			NS	PATIENT REFUSED LUMBAR PUNCTURE
			V6 (WEEK 52)	365	2011-02-28	10:30	ND	2011-02-28	10:30	ND	
	018	5	V1 (WEEK 0)	1	2009-11-23	13:00	ND	2009-11-23	13:15	0.397	
			V3 (WEEK 12)	86	2010-02-16	12:45	ND	2010-02-16	12:45	<LLOQ	
			V6 (WEEK 52)	366	2010-11-23	9:20	ND	2010-12-02	10:00	ND	
	020	5	V1 (WEEK 0)	1	2010-02-22	13:20	ND	2010-02-22	13:00	<LLOQ	
	024	4	V1 (WEEK 0)	1	2010-08-16	9:30	ND	2010-08-16	12:00	ND	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
Placebo	024	4	V3 (WEEK 12)	87	2010-11-10	10:20	ND			NS	PATIENT REFUSED LUMBAR PUNCTURE
			V6 (WEEK 52)	358	2011-08-08	9:30	ND	2011-08-08	12:45	<LLOQ	
	028	20	V1 (WEEK 0)	1	2010-11-26	9:15	ND	2010-11-26	12:10	ND	OPTIONAL, PATIENT DID NOT WANT PATIENT DID NOT TOLERATE LUMBAR PUNCTURE
			V3 (WEEK 12)	89	2011-02-22	10:20	ND			NS	
			V6 (WEEK 52)	364	2011-11-24	8:09	ND			NS	
	029	8	V1 (WEEK 0)	1	2010-01-29	10:00	ND	2010-01-29	13:24	0.359	OPTIONAL PAT DENIED SAMPLING
			V3 (WEEK 12)	82	2010-04-20	11:50	ND			NS	
			V6 (WEEK 52)	369	2011-02-01	11:45	ND			NS	
	031	8	V1 (WEEK 0)	1	2010-05-20	10:00	ND	2010-05-20	13:30	ND	OPTIONAL PATIENT REFUSED CSF SAMPLING
			V3 (WEEK 12)	90							
			V6 (WEEK 52)	363	2011-05-17	11:40	ND			NS	
	034	9	V1 (WEEK 0)	1	2010-03-18	8:50	ND	2010-03-18	12:10	<LLOQ	
			V3 (WEEK 12)	83	2010-06-08	9:10	ND	2010-06-15	11:10	ND	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
Placebo	034	9	V6 (WEEK 52)	363	2011-03-15	8:25	ND	2011-03-15	13:00	<LLOQ	
	041	12	V1 (WEEK 0)	1	2009-10-09	13:15	ND	2009-10-09	13:15	<LLOQ	
			V3 (WEEK 12)	89	2010-01-05	9:40	ND			NS	NOT ACCEPTED BY PATIENT
			V6 (WEEK 52)	363	2010-10-06	8:30	ND	2010-10-06	11:50	ND	
	044	12	V1 (WEEK 0)	1	2009-12-02	9:40	ND			NS	PUNCTURE FAILED
			V3 (WEEK 12)	85	2010-02-24	9:20	ND			NS	NOT ACCEPTED BY PATIENT
			V6 (WEEK 52)	365	2010-12-01	8:15	ND			NS	PUNCTURE FAILED, AGITATION OF PATIENT
	045	11	V1 (WEEK 0)	1	2009-12-21	9:15	ND	2009-12-21	11:15	<LLOQ	
			V3 (WEEK 12)	85							PAT. DID NOT WANT LP
			V6 (WEEK 52)	360	2010-12-15	8:30	ND			NS	PUNCTIO SICCA, NOT POSSIBLE WITH 5 TRIALS
	047	11	V1 (WEEK 0)	1	2010-08-02	8:45	ND	2010-08-02	10:30	ND	
			V3 (WEEK 12)	80	2010-10-20	11:40	ND			NS	PAT. DID NOT WANT LP
			V6 (WEEK 52)	360	2011-07-27	7:35	ND	2011-07-27	11:00	<LLOQ	
	049	21	V1 (WEEK 0)	1	2010-10-27	8:55	ND	2010-10-27	11:00	ND	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
Placebo	049	21	V3 (WEEK 12)	84							PATIENT REFUSED OPTIONAL LUMBAR PUNCTURE
	051	21	V1 (WEEK 0) V3 (WEEK 12)	1 97	2010-10-28	11:30	ND			NS	PUNCTURE FAILED PATIENT REFUSED OPTIONAL LUMBAR PUNCTURE
			V6 (WEEK 52)	363	2011-10-25	8:30	ND	2011-10-25	10:35	ND	
	056	5	V1 (WEEK 0) V3 (WEEK 12)	1 84	2010-04-21 2010-07-13	9:15 11:15	ND ND	2010-04-21	12:10	<LLOQ NS	PATIENT UNDERWENT SPINAL CANAL STENOSIS
			V6 (WEEK 52)	364	2011-04-19	8:05	ND	2011-04-19	12:20	<LLOQ	
	058	1	V1 (WEEK 0) V3 (WEEK 12)	1 93	2010-12-27 2011-03-29	11:15 11:10	ND ND	2010-12-27	13:35	ND NS	PATIENT REFUSED FLUID SAMPLING
			V6 (WEEK 52)	345	2011-12-06	9:15	ND	2011-12-13	10:45	ND	
	059	1	V1 (WEEK 0)	1	2010-12-29	10:05	ND	2010-12-29	12:20	ND	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	Reason for not done
Placebo	059	1	V3 (WEEK 12)	93	2011-03-31	9:40	ND			NS	PATIENT REFUSED CEREBROSPINAL FLUID SAMPLING
			V6 (WEEK 52)	345	2011-12-08	10:00	ND	2011-12-06	10:50	ND	
	065	16	V1 (WEEK 0)	1	2010-08-30	9:05	ND	2010-08-30	9:15	ND	PATIENT NOT GIVEN CONSENT FOR OPTIONAL FLUID SAMPLING
			V3 (WEEK 12)	85	2010-11-22	10:50	ND			NS	
	068	16	V1 (WEEK 0)	1	2010-11-22	10:10	ND	2010-11-22	9:40	ND	IS A OPTIONAL TEST
			V3 (WEEK 12)	81	2011-02-14	9:00	ND			NS	
			V6 (WEEK 52)	372	2011-11-28	10:30	ND	2011-11-28	10:50	ND	
	069	23	V1 (WEEK 0)	1	2010-12-07	12:30	ND	2010-12-07	12:35	ND	OPTIONAL
			V3 (WEEK 12)	93	2011-03-09	12:20	ND			NS	
			V6 (WEEK 52)	373	2011-12-14	9:00	ND	2011-12-14	10:00	ND	
	072	18	V1 (WEEK 0)	1	2010-12-21	12:15	ND	2010-12-21	14:37	ND	CAREGIVER AND PATIENT DID NOT WANT TO
			V3 (WEEK 12)	85	2011-03-15	9:55	ND			NS	

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma			CSF			Reason for not done
					Date	Time	Concen- tration [ng/mL]	Date	Time	Concen- tration [ng/mL]	
Placebo	072	18	V6 (WEEK 52)	360				2011-12-15	14:00		
	079	13	V1 (WEEK 0)	1	2010-08-06	9:50	ND	2010-08-12	12:45	ND	
			V3 (WEEK 12)	96	2010-11-09	11:40	ND	2010-11-09	14:30	ND	
			V6 (WEEK 52)	320	2011-06-21	11:15	ND	2011-06-21	15:20	<LLOQ	
	082	17	V1 (WEEK 0)	1	2010-10-14	9:00	ND	2010-10-14	14:00	ND	OPTIONAL
			V3 (WEEK 12)	84							
			V6 (WEEK 52)	364	2011-10-12	9:15	ND	2011-10-13	10:15	ND	
	084	17	V1 (WEEK 0)	1	2010-11-17	9:15	ND	2010-11-17	14:00	ND	OPTIONAL
			V3 (WEEK 12)	84							
			V6 (WEEK 52)	371	2011-11-22	11:30	NS	2011-11-23	11:00	ND	
	086	21	V1 (WEEK 0)	1	2010-10-28	14:05	ND	2010-10-28	14:50	ND	PATIENT REFUSED OPTIONAL LUMBAR PUNCTURE
			V3 (WEEK 12)	83							
			V6 (WEEK 52)	363	2011-10-25	11:30	ND	2011-10-25	13:40	ND	
	088	16	V1 (WEEK 0)	1	2010-12-09	9:05	ND	2010-12-09	8:45	ND	IS A OPTIONAL SAMPLING
			V3 (WEEK 12)	83							

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Listing 16.2.5.2: Plasma and CSF concentrations of ACI-91

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Treat- ment	Random No.	Site ID	Visit	Actual day	Plasma		Concen- tration [ng/mL]	CSF		Reason for not done
					Date	Time		Date	Time	
Placebo	088	16	V6 (WEEK 52)	376						PATIENT DONT GIVE INFORMED CONSENT

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	002	1	V1 (WEEK 0)	2009-04-23	8:55	Plasma level Aβ1-40	06AUG2010	127.88	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					11:00	Albumin (CSF)	02SEP2011	0.24	YES	
						CSF level Aβ1-40	11AUG2010	8730.65	YES	
						CSF level Aβ1-42	11AUG2010	765.79	YES	
						CSF level F2-Isoprostane	11AUG2010	61.61	YES	
						CSF level Phospho Tau	11AUG2010	149.57	YES	+
						CSF level Tau protein	11AUG2010	>1200	YES	+
			V3 (WEEK 12)	2009-07-16	8:30	Plasma level Aβ1-40	06AUG2010	119.12	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					10:45	Albumin (CSF)	02SEP2011	0.25	YES	
						CSF level Aβ1-40	11AUG2010	7703.05	YES	
						CSF level Aβ1-42	11AUG2010	635.09	YES	
						CSF level F2-Isoprostane	11AUG2010	68.07	YES	
						CSF level Phospho Tau	11AUG2010	148.92	YES	+
						CSF level Tau protein	11AUG2010	>1200	YES	+
			V4 (WEEK 24)	2009-10-08	10:30	Plasma level Aβ1-40	06AUG2010	155.58	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
			V5 (WEEK 36)	2010-01-05	9:25	Plasma level Aβ1-40	06AUG2010	173.31	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
			V6 (WEEK 52)	2010-04-22	10:10	Plasma level Aβ1-40	06AUG2010	104.30	YES	

Classification: -/+ = below/above normal range

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	002	1	V1 (WEEK 0)	2009-04-23	8:55	Plasma level Aβ1-40	06AUG2010	127.88		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					11:00	Albumin (CSF)	02SEP2011	0.24	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	8730.65		pg/mL
						CSF level Aβ1-42	11AUG2010	765.79		pg/mL
						CSF level F2-Isoprostane	11AUG2010	61.61		pg/mL
						CSF level Phospho Tau	11AUG2010	149.57	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
			V3 (WEEK 12)	2009-07-16	8:30	Plasma level Aβ1-40	06AUG2010	119.12		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					10:45	Albumin (CSF)	02SEP2011	0.25	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	7703.05		pg/mL
						CSF level Aβ1-42	11AUG2010	635.09		pg/mL
						CSF level F2-Isoprostane	11AUG2010	68.07		pg/mL
						CSF level Phospho Tau	11AUG2010	148.92	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
			V4 (WEEK 24)	2009-10-08	10:30	Plasma level Aβ1-40	06AUG2010	155.58		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V5 (WEEK 36)	2010-01-05	9:25	Plasma level Aβ1-40	06AUG2010	173.31		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V6 (WEEK 52)	2010-04-22	10:10	Plasma level Aβ1-40	06AUG2010	104.30		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	002	1	V6 (WEEK 52)	2010-04-22	10:10	Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					12:00	Albumin (CSF)	02SEP2011	0.26	YES	
						CSF level Aβ1-40	11AUG2010	7127.70	YES	
						CSF level Aβ1-42	11AUG2010	640.28	YES	
						CSF level F2-Isoprostane	11AUG2010	56.86	YES	
						CSF level Phospho Tau	11AUG2010	139.62	YES	+
						CSF level Tau protein	11AUG2010	>1200	YES	+
			V7 (WEEK 56)	2010-05-20	9:15	Plasma level Aβ1-40	06AUG2010	134.41	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
	004	1	V1 (WEEK 0)	2009-07-16	10:00	Plasma level Aβ1-40	06AUG2010	103.87	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					11:45	Albumin (CSF)	02SEP2011	0.42	YES	+
						CSF level Aβ1-40	11AUG2010	7028.70	YES	
						CSF level Aβ1-42	11AUG2010	>1000.00	YES	
						CSF level F2-Isoprostane	11AUG2010	73.61	YES	
						CSF level Phospho Tau	11AUG2010	76.53	YES	+
						CSF level Tau protein	11AUG2010	629.19	YES	+
			V3 (WEEK 12)	2009-10-15	14:50	Plasma level Aβ1-40	06AUG2010	146.91	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	002	1	V6 (WEEK 52)	2010-04-22	10:10	Plasma level Aβ1-42	06AUG2010	<29.00	0.10 - 0.3	pg/mL
					12:00	Albumin (CSF)	02SEP2011	0.26		g/L
						CSF level Aβ1-40	11AUG2010	7127.70		pg/mL
						CSF level Aβ1-42	11AUG2010	640.28		pg/mL
						CSF level F2-Isoprostane	11AUG2010	56.86		pg/mL
						CSF level Phospho Tau	11AUG2010	139.62		pg/mL
	004	1	V1 (WEEK 0)	2009-07-16	10:00	CSF level Tau protein	11AUG2010	>1200	< 61 116 - 360	ng/L
						Plasma level Aβ1-40	06AUG2010	134.41		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V7 (WEEK 56)	2010-05-20	9:15	Plasma level Aβ1-40	06AUG2010	134.41		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V3 (WEEK 12)	2009-10-15	14:50	Plasma level Aβ1-40	06AUG2010	146.91		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V3 (WEEK 12)	2009-10-15	14:50	Plasma level Aβ1-40	06AUG2010	146.91		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	006	2	V1 (WEEK 0)	2010-02-26	9:00	Plasma level Aβ1-40	06AUG2010	84.60		
							02SEP2011	130.16	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
					10:00	Albumin (CSF)	02SEP2011	0.33	YES	+
						CSF level Aβ1-40	11AUG2010	5542.00		
							11AUG2011	5684.20	YES	
						CSF level Aβ1-42	11AUG2010	616.29		
							11AUG2011	670.19	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	106.13		+
							11AUG2011	90.47	YES	+
						CSF level Tau protein	11AUG2010	1147.05		+
							11AUG2011	735.92	YES	+
			V3 (WEEK 12)	2010-05-21	9:15	Plasma level Aβ1-40	06AUG2010	85.73		
							02SEP2011	132.60	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
					10:00	Albumin (CSF)	02SEP2011	0.30	YES	+
						CSF level Aβ1-40	11AUG2010	5533.65		
							11AUG2011	6031.40	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	006	2	V1 (WEEK 0)	2010-02-26	9:00	Plasma level Aβ1-40	06AUG2010	84.60		pg/mL
							02SEP2011	130.16		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
					10:00	Albumin (CSF)	02SEP2011	0.33	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	5542.00		pg/mL
							11AUG2011	5684.20		pg/mL
						CSF level Aβ1-42	11AUG2010	616.29		pg/mL
							11AUG2011	670.19		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	106.13	< 61	pg/mL
							11AUG2011	90.47	< 61	pg/mL
						CSF level Tau protein	11AUG2010	1147.05	116 - 360	ng/L
							11AUG2011	735.92	116 - 360	ng/L
			V3 (WEEK 12)	2010-05-21	9:15	Plasma level Aβ1-40	06AUG2010	85.73		pg/mL
							02SEP2011	132.60		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
					10:00	Albumin (CSF)	02SEP2011	0.30	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	5533.65		pg/mL
							11AUG2011	6031.40		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	006	2	V3 (WEEK 12)	2010-05-21	10:00	CSF level Aβ1-42	11AUG2010	546.49		
							11AUG2011	732.61	YES	
						CSF level F2-Isoprostane	11AUG2010	54.77	YES	
						CSF level Phospho Tau	11AUG2010	108.72		+
							11AUG2011	94.21	YES	+
			V4 (WEEK 24)	2010-08-13	9:00	CSF level Tau protein	11AUG2010	>1200		+
							11AUG2011	819.80	YES	+
						Plasma level Aβ1-40	04AUG2011	185.00	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V5 (WEEK 36)	2010-11-04	8:30	Plasma level Aβ1-40	04AUG2011	136.55	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-02-24	8:20	Plasma level Aβ1-40	04AUG2011	108.33	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
					9:00	Albumin (CSF)	02SEP2011	0.28	YES	
						CSF level Aβ1-40	11AUG2011	6964.60	YES	
						CSF level Aβ1-42	11AUG2011	792.78	YES	
						CSF level Phospho Tau	11AUG2011	92.96	YES	+
						CSF level Tau protein	11AUG2011	780.53	YES	+
						Plasma level Aβ1-40	04AUG2011	117.51	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	006	2	V3 (WEEK 12)	2010-05-21	10:00	CSF level Aβ1-42	11AUG2010	546.49		pg/mL
							11AUG2011	732.61		pg/mL
						CSF level F2-Isoprostane	11AUG2010	54.77		pg/mL
						CSF level Phospho Tau	11AUG2010	108.72	< 61	pg/mL
							11AUG2011	94.21	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
							11AUG2011	819.80	116 - 360	ng/L
							04AUG2011	185.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V5 (WEEK 36)	2010-11-04	8:30	Plasma level Aβ1-40	04AUG2011	136.55		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-02-24	8:20	Plasma level Aβ1-40	04AUG2011	108.33		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
							02SEP2011	0.28	0.10 - 0.3	g/L
						Albumin (CSF)	11AUG2011	6964.60		pg/mL
						CSF level Aβ1-40	11AUG2011	792.78		pg/mL
						CSF level Aβ1-42	11AUG2011	92.96	< 61	pg/mL
						CSF level Phospho Tau	11AUG2011	780.53	170 - 512	ng/L
						CSF level Tau protein	11AUG2011	117.51		pg/mL
			V7 (WEEK 56)	2011-03-22	8:30	Plasma level Aβ1-40	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	010	1	V1 (WEEK 0)	2009-07-21	11:00	Plasma level Aβ1-40	06AUG2010	100.15	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					12:30	Albumin (CSF)	02SEP2011	0.37	YES	+
						CSF level Aβ1-40	11AUG2010	5138.05	YES	
						CSF level Aβ1-42	11AUG2010	610.54	YES	
						CSF level F2-Isoprostane	11AUG2010	68.48	YES	
						CSF level Phospho Tau	11AUG2010	81.69	YES	+
						CSF level Tau protein	11AUG2010	712.24	YES	+
			V3 (WEEK 12)	2009-10-13	10:45	Plasma level Aβ1-40	06AUG2010	98.90	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					11:25	Albumin (CSF)	02SEP2011	0.36	YES	+
						CSF level Aβ1-40	11AUG2010	6000.55	YES	
						CSF level Aβ1-42	11AUG2010	840.37	YES	
						CSF level F2-Isoprostane	11AUG2010	55.69	YES	
						CSF level Phospho Tau	11AUG2010	88.38	YES	+
						CSF level Tau protein	11AUG2010	834.29	YES	+
	012	1	V1 (WEEK 0)	2010-07-19	10:00	Plasma level Aβ1-40	24AUG2011	69.69	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
					11:10	Albumin (CSF)	02SEP2011	0.46	YES	++
						CSF level Aβ1-40	11AUG2010	8146.90		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	010	1	V1 (WEEK 0)	2009-07-21	11:00	Plasma level Aβ1-40	06AUG2010	100.15		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					12:30	Albumin (CSF)	02SEP2011	0.37	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	5138.05		pg/mL
						CSF level Aβ1-42	11AUG2010	610.54		pg/mL
						CSF level F2-Isoprostane	11AUG2010	68.48		pg/mL
			V3 (WEEK 12)	2009-10-13	10:45	CSF level Phospho Tau	11AUG2010	81.69	< 61	pg/mL
						CSF level Tau protein	11AUG2010	712.24	170 - 512	ng/L
						Plasma level Aβ1-40	06AUG2010	98.90		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					11:25	Albumin (CSF)	02SEP2011	0.36	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	6000.55		pg/mL
						CSF level Aβ1-42	11AUG2010	840.37		pg/mL
						CSF level F2-Isoprostane	11AUG2010	55.69		pg/mL
						CSF level Phospho Tau	11AUG2010	88.38	< 61	pg/mL
						CSF level Tau protein	11AUG2010	834.29	170 - 512	ng/L
	012	1	V1 (WEEK 0)	2010-07-19	10:00	Plasma level Aβ1-40	24AUG2011	69.69		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
					11:10	Albumin (CSF)	02SEP2011	0.46	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	8146.90		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	012	1	V1 (WEEK 0)	2010-07-19	11:10	CSF level Aβ1-40	11AUG2011	8789.40	YES	
						CSF level Aβ1-42	11AUG2010	849.06		
							11AUG2011	786.79	YES	
						CSF level F2-Isoprostane	11AUG2010	50.13	YES	
						CSF level Phospho Tau	11AUG2010	96.95		+
							11AUG2011	76.30	YES	+
						CSF level Tau protein	11AUG2010	842.98		+
							11AUG2011	477.71	YES	
			V3 (WEEK 12)	2010-10-14	9:15	Plasma level Aβ1-40	24AUG2011	84.21	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V4 (WEEK 24)	2011-01-10	10:50	Plasma level Aβ1-40	24AUG2011	94.26	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V5 (WEEK 36)	2011-04-01	9:30	Plasma level Aβ1-40	24AUG2011	78.61	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-07-14	10:25	Plasma level Aβ1-40	24AUG2011	79.46	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
					11:00	Albumin (CSF)	02SEP2011	0.61	YES	++
						CSF level Aβ1-40	11AUG2011	6486.20	YES	
						CSF level Aβ1-42	11AUG2011	773.18	YES	
						CSF level Phospho Tau	11AUG2011	77.98	YES	+
						CSF level Tau protein	11AUG2011	500.38	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	012	1	V1 (WEEK 0)	2010-07-19	11:10	CSF level Aβ1-40	11AUG2011	8789.40		pg/mL
						CSF level Aβ1-42	11AUG2010	849.06		pg/mL
							11AUG2011	786.79		pg/mL
						CSF level F2-Isoprostane	11AUG2010	50.13		pg/mL
						CSF level Phospho Tau	11AUG2010	96.95	< 61	pg/mL
			V3 (WEEK 12)	2010-10-14	9:15		11AUG2011	76.30	< 61	pg/mL
						CSF level Tau protein	11AUG2010	842.98	170 - 512	ng/L
							11AUG2011	477.71	170 - 512	ng/L
						Plasma level Aβ1-40	24AUG2011	84.21		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
			V4 (WEEK 24)	2011-01-10	10:50	Plasma level Aβ1-40	24AUG2011	94.26		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
			V5 (WEEK 36)	2011-04-01	9:30	Plasma level Aβ1-40	24AUG2011	78.61		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-07-14	10:25	Plasma level Aβ1-40	24AUG2011	79.46		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
					11:00	Albumin (CSF)	02SEP2011	0.61	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	6486.20		pg/mL
						CSF level Aβ1-42	11AUG2011	773.18		pg/mL
						CSF level Phospho Tau	11AUG2011	77.98	< 61	pg/mL
						CSF level Tau protein	11AUG2011	500.38	170 - 512	ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	012	1	V7 (WEEK 56)	2011-08-18	12:20	Plasma level Aβ1-40	24AUG2011	75.77	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
	014	4	V1 (WEEK 0)	2009-11-02	9:30	Plasma level Aβ1-40	06AUG2010	86.98		
						Plasma level Aβ1-42	02SEP2011	137.02	YES	
							06AUG2010	<29.00		
							02SEP2011	221.33	YES	
					12:30	Albumin (CSF)	02SEP2011	0.21	YES	
						CSF level Aβ1-40	11AUG2010	8330.30		
							11AUG2011	9594.90	YES	
						CSF level Aβ1-42	11AUG2010	837.65		
							11AUG2011	807.25	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	123.49		+
							11AUG2011	103.19	YES	+
						CSF level Tau protein	11AUG2010	1164.50		+
							11AUG2011	775.81	YES	+
			V3 (WEEK 12)	2010-01-25	10:00	Plasma level Aβ1-40	06AUG2010	73.91		
							02SEP2011	84.62	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	249.03	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	012	1	V7 (WEEK 56)	2011-08-18	12:20	Plasma level Aβ1-40	24AUG2011	75.77		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
	014	4	V1 (WEEK 0)	2009-11-02	9:30	Plasma level Aβ1-40	06AUG2010	86.98		pg/mL
							02SEP2011	137.02		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	221.33		pg/mL
					12:30	Albumin (CSF)	02SEP2011	0.21	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	8330.30		pg/mL
							11AUG2011	9594.90		pg/mL
						CSF level Aβ1-42	11AUG2010	837.65		pg/mL
							11AUG2011	807.25		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	123.49	< 61	pg/mL
							11AUG2011	103.19	< 61	pg/mL
						CSF level Tau protein	11AUG2010	1164.50	170 - 512	ng/L
							11AUG2011	775.81	170 - 512	ng/L
			V3 (WEEK 12)	2010-01-25	10:00	Plasma level Aβ1-40	06AUG2010	73.91		pg/mL
							02SEP2011	84.62		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	249.03		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	014	4	V4 (WEEK 24)	2010-04-22	10:15	Plasma level Aβ1-40	06AUG2010	109.63		
							02SEP2011	167.02	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	394.11	YES	
			V5 (WEEK 36)	2010-07-15	10:30	Plasma level Aβ1-40	04AUG2011	80.98	YES	
						Plasma level Aβ1-42	04AUG2011	>500.00	YES	
						Plasma level Aβ1-40	04AUG2011	134.28	YES	
						Plasma level Aβ1-42	04AUG2011	323.80	YES	
			V6 (WEEK 52)	2010-10-28	11:00	Albumin (CSF)	02SEP2011	0.18	YES	
						CSF level Aβ1-40	11AUG2011	10981.00	YES	
						CSF level Aβ1-42	11AUG2011	898.04	YES	
						CSF level Phospho Tau	11AUG2011	112.11	YES	+
						CSF level Tau protein	11AUG2011	750.69	YES	+
					11:50	Plasma level Aβ1-40	04AUG2011	136.28	YES	
						Plasma level Aβ1-42	04AUG2011	287.97	YES	
			V7 (WEEK 56)	2010-12-02	11:30					
	015	4	V1 (WEEK 0)	2010-02-22	9:00	Plasma level Aβ1-40	06AUG2010	74.61		
							02SEP2011	119.27	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.24	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	014	4	V4 (WEEK 24)	2010-04-22	10:15	Plasma level Aβ1-40	06AUG2010	109.63		pg/mL
							02SEP2011	167.02		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	394.11		pg/mL
			V5 (WEEK 36)	2010-07-15	10:30	Plasma level Aβ1-40	04AUG2011	80.98		pg/mL
						Plasma level Aβ1-42	04AUG2011	>500.00		pg/mL
			V6 (WEEK 52)	2010-10-28	11:00	Plasma level Aβ1-40	04AUG2011	134.28		pg/mL
						Plasma level Aβ1-42	04AUG2011	323.80		pg/mL
					11:50	Albumin (CSF)	02SEP2011	0.18	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	10981.00		pg/mL
						CSF level Aβ1-42	11AUG2011	898.04		pg/mL
						CSF level Phospho Tau	11AUG2011	112.11	< 61	pg/mL
						CSF level Tau protein	11AUG2011	750.69	170 - 512	ng/L
			V7 (WEEK 56)	2010-12-02	11:30	Plasma level Aβ1-40	04AUG2011	136.28		pg/mL
						Plasma level Aβ1-42	04AUG2011	287.97		pg/mL
	015	4	V1 (WEEK 0)	2010-02-22	9:00	Plasma level Aβ1-40	06AUG2010	74.61		pg/mL
							02SEP2011	119.27		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.24	0.10 - 0.3	g/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	015	4	V1 (WEEK 0)	2010-02-22	11:30	CSF level Aβ1-40	11AUG2010	8195.60		
							01SEP2011	7040.40	YES	
						CSF level Aβ1-42	11AUG2010	933.19		
							01SEP2011	864.11	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
			V3 (WEEK 12)	2010-05-17	10:00	CSF level Phospho Tau	11AUG2010	78.81		+
							01SEP2011	64.74	YES	+
						CSF level Tau protein	11AUG2010	798.86		+
							01SEP2011	421.09	YES	
						Plasma level Aβ1-40	06AUG2010	84.42		
							02SEP2011	132.80	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
			V4 (WEEK 24)	2010-08-02	9:30	Plasma level Aβ1-40	04AUG2011	192.30	YES	
						Plasma level Aβ1-42	04AUG2011	40.08	YES	
			V5 (WEEK 36)	2010-10-27	9:45	Plasma level Aβ1-40	04AUG2011	130.71	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-02-21	10:30	Plasma level Aβ1-40	04AUG2011	134.88	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
					12:00	Albumin (CSF)	02SEP2011	0.25	YES	
						CSF level Aβ1-40	11AUG2011	6514.80	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	015	4	V1 (WEEK 0)	2010-02-22	11:30	CSF level Aβ1-40	11AUG2010	8195.60		pg/mL
							01SEP2011	7040.40		pg/mL
						CSF level Aβ1-42	11AUG2010	933.19		pg/mL
							01SEP2011	864.11		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	78.81	< 61	pg/mL
							01SEP2011	64.74	< 61	pg/mL
						CSF level Tau protein	11AUG2010	798.86	170 - 512	ng/L
							01SEP2011	421.09	170 - 512	ng/L
			V3 (WEEK 12)	2010-05-17	10:00	Plasma level Aβ1-40	06AUG2010	84.42		pg/mL
							02SEP2011	132.80		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
			V4 (WEEK 24)	2010-08-02	9:30	Plasma level Aβ1-40	04AUG2011	192.30		pg/mL
						Plasma level Aβ1-42	04AUG2011	40.08		pg/mL
			V5 (WEEK 36)	2010-10-27	9:45	Plasma level Aβ1-40	04AUG2011	130.71		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-02-21	10:30	Plasma level Aβ1-40	04AUG2011	134.88		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
					12:00	Albumin (CSF)	02SEP2011	0.25	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	6514.80		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	015	4	V6 (WEEK 52)	2011-02-21	12:00	CSF level Aβ1-42	11AUG2011	841.78	YES	+
						CSF level Phospho Tau	11AUG2011	64.38	YES	
						CSF level Tau protein	11AUG2011	461.32	YES	
			V7 (WEEK 56)	2011-03-22	10:15	Plasma level Aβ1-40	04AUG2011	128.12	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	017	5	V1 (WEEK 0)	2009-08-05	9:00	Plasma level Aβ1-40	06AUG2010	114.48		
							02SEP2011	159.60	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
					13:25	Albumin (CSF)	02SEP2011	0.23	YES	
						CSF level Aβ1-40	11AUG2010	7111.60		
							11AUG2011	6197.30	YES	
						CSF level Aβ1-42	11AUG2010	756.66		
							11AUG2011	701.68	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	101.30		
							11AUG2011	82.36	YES	
						CSF level Tau protein	11AUG2010	>1200		
							11AUG2011	1941.20	YES	
			V3 (WEEK 12)	2009-10-28	8:45	Plasma level Aβ1-40	06AUG2010	122.94		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	015	4	V6 (WEEK 52)	2011-02-21	12:00	CSF level Aβ1-42	11AUG2011	841.78	< 61 170 - 512	pg/mL
						CSF level Phospho Tau	11AUG2011	64.38		pg/mL
						CSF level Tau protein	11AUG2011	461.32		ng/L
			V7 (WEEK 56)	2011-03-22	10:15	Plasma level Aβ1-40	04AUG2011	128.12		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	017	5	V1 (WEEK 0)	2009-08-05	9:00	Plasma level Aβ1-40	06AUG2010	114.48	0.10 - 0.3	pg/mL
							02SEP2011	159.60		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.23		g/L
					13:25	CSF level Aβ1-40	11AUG2010	7111.60		pg/mL
							11AUG2011	6197.30		pg/mL
						CSF level Aβ1-42	11AUG2010	756.66		pg/mL
							11AUG2011	701.68		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
					CSF level Phospho Tau	11AUG2010	101.30	< 61	pg/mL	
						11AUG2011	82.36	< 61	pg/mL	
					CSF level Tau protein	11AUG2010	>1200	170 - 512	ng/L	
						11AUG2011	1941.20	170 - 512	ng/L	
						06AUG2010	122.94	pg/mL		
		V3 (WEEK 12)	2009-10-28	8:45	Plasma level Aβ1-40	06AUG2010	122.94		pg/mL	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	017	5	V3 (WEEK 12)	2009-10-28	8:45	Plasma level Aβ1-40	02SEP2011	160.68	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.30	YES	
					13:30	CSF level Aβ1-40	11AUG2010	4822.20		
							11AUG2011	3946.10	YES	
						CSF level Aβ1-42	11AUG2010	480.53		
							11AUG2011	409.81	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	85.10		+
							11AUG2011	71.45	YES	+
						CSF level Tau protein	11AUG2010	933.32		+
							11AUG2011	511.48	YES	
			V4 (WEEK 24)	2010-01-20	9:00	Plasma level Aβ1-40	06AUG2010	124.50		
							02SEP2011	173.13	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
			V5 (WEEK 36)	2010-04-13	10:45		02SEP2011	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	130.68		
							02SEP2011	185.98	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	017	5	V3 (WEEK 12)	2009-10-28	8:45	Plasma level Aβ1-40	02SEP2011	160.68		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.30	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	4822.20		pg/mL
							11AUG2011	3946.10		pg/mL
						CSF level Aβ1-42	11AUG2010	480.53		pg/mL
							11AUG2011	409.81		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	85.10	< 61	pg/mL
							11AUG2011	71.45	< 61	pg/mL
						CSF level Tau protein	11AUG2010	933.32	170 - 512	ng/L
							11AUG2011	511.48	170 - 512	ng/L
			V4 (WEEK 24)	2010-01-20	9:00	Plasma level Aβ1-40	06AUG2010	124.50		pg/mL
							02SEP2011	173.13		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V5 (WEEK 36)	2010-04-13	10:45		02SEP2011	<29.00		pg/mL
						Plasma level Aβ1-40	06AUG2010	130.68		pg/mL
							02SEP2011	185.98		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	017	5	V6 (WEEK 52)	2010-08-03	9:00	Plasma level Aβ1-40	04AUG2011	105.73	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
					11:00	Albumin (CSF)	02SEP2011	0.26	YES	
						CSF level Aβ1-40	11AUG2011	2546.60	YES	
						CSF level Aβ1-42	11AUG2011	284.54	YES	
						CSF level Phospho Tau	11AUG2011	63.04	YES	+
			V7 (WEEK 56)	2010-08-31	9:00	CSF level Tau protein	11AUG2011	516.40	YES	+
						Plasma level Aβ1-40	04AUG2011	124.86	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	019	5	V1 (WEEK 0)	2009-12-09	9:00	Plasma level Aβ1-40	06AUG2010	154.97		
							02SEP2011	193.34	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.29	YES	
						CSF level Aβ1-40	11AUG2010	6349.65		
							01SEP2011	6147.90	YES	
						CSF level Aβ1-42	11AUG2010	645.26		
							01SEP2011	536.55	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	82.08		+

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	017	5	V6 (WEEK 52)	2010-08-03	9:00	Plasma level Aβ1-40	04AUG2011	105.73		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
					11:00	Albumin (CSF)	02SEP2011	0.26	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	2546.60		pg/mL
						CSF level Aβ1-42	11AUG2011	284.54		pg/mL
						CSF level Phospho Tau	11AUG2011	63.04	< 61	pg/mL
						CSF level Tau protein	11AUG2011	516.40	170 - 512	ng/L
			V7 (WEEK 56)	2010-08-31	9:00	Plasma level Aβ1-40	04AUG2011	124.86		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	019	5	V1 (WEEK 0)	2009-12-09	9:00	Plasma level Aβ1-40	06AUG2010	154.97		pg/mL
							02SEP2011	193.34		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
					13:30	Albumin (CSF)	02SEP2011	0.29	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	6349.65		pg/mL
							01SEP2011	6147.90		pg/mL
						CSF level Aβ1-42	11AUG2010	645.26		pg/mL
							01SEP2011	536.55		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	82.08	< 61	pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	019	5	V1 (WEEK 0)	2009-12-09	13:30	CSF level Phospho Tau	01SEP2011	67.55	YES	+
						CSF level Tau protein	11AUG2010	737.72		+
			V3 (WEEK 12)	2010-03-03	9:00	Plasma level Aβ1-40	01SEP2011	420.70	YES	
							06AUG2010	145.55		
						Plasma level Aβ1-42	02SEP2011	189.70	YES	
							06AUG2010	<29.00		
						Albumin (CSF)	02SEP2011	<29.00	YES	
							02SEP2011	0.33	YES	+
					13:15	CSF level Aβ1-40	11AUG2010	5746.55		
						CSF level Aβ1-42	11AUG2011	6109.40	YES	
							11AUG2010	574.46		
						CSF level F2-Isoprostane	11AUG2011	597.48	YES	
							11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	76.38		+
						CSF level Tau protein	11AUG2011	67.68	YES	+
							11AUG2010	726.36		+
			V4 (WEEK 24)	2010-05-25	9:00	Plasma level Aβ1-40	11AUG2011	432.57	YES	
						Plasma level Aβ1-42	04AUG2011	210.31	YES	
			V6 (WEEK 52)	2010-12-07	13:30	Albumin (CSF)	04AUG2011	<29.00	YES	
						CSF level Aβ1-40	02SEP2011	0.31	YES	+
							11AUG2011	6163.50	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	019	5	V1 (WEEK 0)	2009-12-09	13:30	CSF level Phospho Tau	01SEP2011	67.55	< 61	pg/mL
						CSF level Tau protein	11AUG2010	737.72	170 - 512	ng/L
							01SEP2011	420.70	170 - 512	ng/L
			V3 (WEEK 12)	2010-03-03	9:00	Plasma level Aβ1-40	06AUG2010	145.55		pg/mL
							02SEP2011	189.70		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.33	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	5746.55		pg/mL
					13:15		11AUG2011	6109.40		pg/mL
						CSF level Aβ1-42	11AUG2010	574.46		pg/mL
							11AUG2011	597.48		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	76.38	< 61	pg/mL
							11AUG2011	67.68	< 61	pg/mL
						CSF level Tau protein	11AUG2010	726.36	170 - 512	ng/L
							11AUG2011	432.57	170 - 512	ng/L
			V4 (WEEK 24)	2010-05-25	9:00	Plasma level Aβ1-40	04AUG2011	210.31		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2010-12-07	13:30	Albumin (CSF)	02SEP2011	0.31	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	6163.50		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling			Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time	Parameter				
ACI-91	019	5	V6 (WEEK 52)	2010-12-07	13:30	CSF level Aβ1-42	11AUG2011	591.61	YES	+
						CSF level Phospho Tau	11AUG2011	63.40	YES	
						CSF level Tau protein	11AUG2011	356.36	YES	
						Plasma level Aβ1-40	04AUG2011	150.94	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
						V7 (WEEK 56)	2011-01-11	9:10	Plasma level Aβ1-40	
			Plasma level Aβ1-42	04AUG2011	<29.00	YES				
	023	4	V1 (WEEK 0)	2010-07-20	10:00	Plasma level Aβ1-40	24AUG2011	<16.00	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.23	YES	
						CSF level Aβ1-40	11AUG2010	4999.55		
							11AUG2011	2951.20	YES	
						CSF level Aβ1-42	11AUG2010	542.62		
							11AUG2011	425.78	YES	
CSF level F2-Isoprostane	11AUG2010	<50.00	YES	+						
CSF level Phospho Tau	11AUG2010	115.25								
	11AUG2011	100.99	YES		+					
					CSF level Tau protein	11AUG2010	>1200		+	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	019	5	V6 (WEEK 52)	2010-12-07	13:30	CSF level Aβ1-42	11AUG2011	591.61		pg/mL
						CSF level Phospho Tau	11AUG2011	63.40	< 61	pg/mL
						CSF level Tau protein	11AUG2011	356.36	170 - 512	ng/L
						Plasma level Aβ1-40	04AUG2011	150.94		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	151.55		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	023	4	V1 (WEEK 0)	2010-07-20	10:00	Plasma level Aβ1-40	24AUG2011	<16.00		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.23	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	4999.55		pg/mL
					12:00	CSF level Aβ1-42	11AUG2011	2951.20		pg/mL
						CSF level Aβ1-42	11AUG2010	542.62		pg/mL
						CSF level Aβ1-42	11AUG2011	425.78		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	115.25	< 61	pg/mL
						CSF level Phospho Tau	11AUG2011	100.99	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Comment
				Date	Time				
ACI-91	019	5	V6 (WEEK 52)	2010-12-07	13:30	CSF level Aβ1-42	11AUG2011	591.61	
						CSF level Phospho Tau	11AUG2011	63.40	
						CSF level Tau protein	11AUG2011	356.36	
						Plasma level Aβ1-40	04AUG2011	150.94	
			V7 (WEEK 56)	2011-01-11	9:10	Plasma level Aβ1-42	04AUG2011	<29.00	
						Plasma level Aβ1-40	04AUG2011	151.55	
	023	4	V1 (WEEK 0)	2010-07-20	10:00	Plasma level Aβ1-40	24AUG2011	<16.00	
						Plasma level Aβ1-42	24AUG2011	<29.00	
					12:00	Albumin (CSF)	02SEP2011	0.23	
						CSF level Aβ1-40	11AUG2010	4999.55	
							11AUG2011	2951.20	
						CSF level Aβ1-42	11AUG2010	542.62	
							11AUG2011	425.78	
						CSF level F2-Isoprostane	11AUG2010	<50.00	
CSF level Phospho Tau	11AUG2010	115.25							
	11AUG2011	100.99							
	CSF level Tau protein	11AUG2010	>1200						

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	023	4	V1 (WEEK 0)	2010-07-20	12:00	CSF level Tau protein	11AUG2011	797.83	YES	+
			V3 (WEEK 12)	2010-10-13	9:30	Plasma level Aβ1-40	24AUG2011	93.18	YES	
			V4 (WEEK 24)	2011-01-12	10:30	Plasma level Aβ1-42	24AUG2011	<29.00	YES	
						Plasma level Aβ1-40	24AUG2011	102.39	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V5 (WEEK 36)	2011-03-21	9:45	Plasma level Aβ1-40	24AUG2011	91.01	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
						Plasma level Aβ1-40	24AUG2011	100.37	YES	
			V6 (WEEK 52)	2011-07-18	10:00	Plasma level Aβ1-40	24AUG2011	<29.00	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.21	YES	
					12:45	CSF level Aβ1-40	11AUG2011	6430.60	YES	
						CSF level Aβ1-42	11AUG2011	771.92	YES	
						CSF level Phospho Tau	11AUG2011	97.85	YES	
						CSF level Tau protein	11AUG2011	933.53	YES	
			V7 (WEEK 56)	2011-08-11	11:15	Plasma level Aβ1-40	24AUG2011	96.75	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
	027	20	V1 (WEEK 0)	2010-10-21	9:15	Plasma level Aβ1-40	28FEB2012	109.90	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					12:30	Albumin (CSF)	27FEB2012	0.16	YES	
						CSF level Aβ1-40	27FEB2012	8459.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	023	4	V1 (WEEK 0)	2010-07-20	12:00	CSF level Tau protein	11AUG2011	797.83	116 - 360	ng/L
			V3 (WEEK 12)	2010-10-13	9:30	Plasma level Aβ1-40	24AUG2011	93.18		pg/mL
			V4 (WEEK 24)	2011-01-12	10:30	Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	24AUG2011	102.39		pg/mL
			V5 (WEEK 36)	2011-03-21	9:45	Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	24AUG2011	91.01		pg/mL
			V6 (WEEK 52)	2011-07-18	10:00	Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	24AUG2011	100.37		pg/mL
			V7 (WEEK 56)	2011-08-11	11:15	Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.21	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	6430.60		pg/mL
						CSF level Aβ1-42	11AUG2011	771.92		pg/mL
						CSF level Phospho Tau	11AUG2011	97.85	< 61	pg/mL
						CSF level Tau protein	11AUG2011	933.53	116 - 360	ng/L
						Plasma level Aβ1-40	24AUG2011	96.75		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
	027	20	V1 (WEEK 0)	2010-10-21	9:15	Plasma level Aβ1-40	28FEB2012	109.90		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					12:30	Albumin (CSF)	27FEB2012	0.16	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	8459.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	027	20	V1 (WEEK 0)	2010-10-21	12:30	CSF level Aβ1-42	27FEB2012	1309.20	YES	
						CSF level Phospho Tau	27FEB2012	46.86	YES	
						CSF level Tau protein	27FEB2012	313.48	YES	
			V4 (WEEK 24)	2011-04-12	10:30	Plasma level Aβ1-40	28FEB2012	117.21	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-07-06	10:55	Plasma level Aβ1-40	28FEB2012	132.38	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	112.46	YES	
			V6 (WEEK 52)	2011-10-25	8:19	Plasma level Aβ1-40	28FEB2012	112.46	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					13:45	Albumin (CSF)	27FEB2012	0.16	YES	
						CSF level Aβ1-40	27FEB2012	8795.30	YES	
						CSF level Aβ1-42	27FEB2012	1406.70	YES	
						CSF level Phospho Tau	27FEB2012	46.68	YES	
			V7 (WEEK 56)	2011-12-01	10:10	CSF level Tau protein	27FEB2012	317.60	YES	
						Plasma level Aβ1-40	28FEB2012	115.55	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	030	8	V1 (WEEK 0)	2010-03-25	10:20	Plasma level Aβ1-40	06AUG2010	86.04		
							02SEP2011	121.04	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	027	20	V1 (WEEK 0)	2010-10-21	12:30	CSF level Aβ1-42	27FEB2012	1309.20		pg/mL
						CSF level Phospho Tau	27FEB2012	46.86	< 61	pg/mL
						CSF level Tau protein	27FEB2012	313.48	116 - 360	ng/L
						Plasma level Aβ1-40	28FEB2012	117.21		pg/mL
			V4 (WEEK 24)	2011-04-12	10:30	Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	132.38		pg/mL
			V5 (WEEK 36)	2011-07-06	10:55	Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	112.46		pg/mL
			V6 (WEEK 52)	2011-10-25	8:19	Plasma level Aβ1-40	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					13:45	Albumin (CSF)	27FEB2012	0.16	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	8795.30		pg/mL
			V7 (WEEK 56)	2011-12-01	10:10	CSF level Aβ1-42	27FEB2012	1406.70		pg/mL
						CSF level Phospho Tau	27FEB2012	46.68	< 61	pg/mL
						CSF level Tau protein	27FEB2012	317.60	116 - 360	ng/L
						Plasma level Aβ1-40	28FEB2012	115.55		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	030	8	V1 (WEEK 0)	2010-03-25	10:20	Plasma level Aβ1-40	06AUG2010	86.04		pg/mL
							02SEP2011	121.04		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	030	8	V1 (WEEK 0)	2010-03-25	12:45	Albumin (CSF)	02SEP2011	0.16	YES	
						CSF level Aβ1-40	11AUG2010	6887.65		
							11AUG2011	6227.40	YES	
						CSF level Aβ1-42	11AUG2010	856.75		
							11AUG2011	727.21	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	129.36		+
							11AUG2011	107.24	YES	+
						CSF level Tau protein	11AUG2010	>1200		+
							11AUG2011	883.50	YES	+
			V3 (WEEK 12)	2010-06-17	11:50	Plasma level Aβ1-40	06AUG2010	89.81		
							02SEP2011	135.71	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
			V4 (WEEK 24)	2010-09-03	12:30	Plasma level Aβ1-40	04AUG2011	164.75	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V5 (WEEK 36)	2010-12-02	12:50	Plasma level Aβ1-40	04AUG2011	173.00	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-03-14	11:00	Plasma level Aβ1-40	04AUG2011	122.52	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
							02SEP2011	0.18	YES	
					14:15	Albumin (CSF)				

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	030	8	V1 (WEEK 0)	2010-03-25	12:45	Albumin (CSF)	02SEP2011	0.16	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	6887.65		pg/mL
							11AUG2011	6227.40		pg/mL
						CSF level Aβ1-42	11AUG2010	856.75		pg/mL
							11AUG2011	727.21		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	129.36		pg/mL
							11AUG2011	107.24		pg/mL
						CSF level Tau protein	11AUG2010	>1200		ng/L
							11AUG2011	883.50		ng/L
			V3 (WEEK 12)	2010-06-17	11:50	Plasma level Aβ1-40	06AUG2010	89.81	116 - 360	pg/mL
							02SEP2011	135.71		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
			V4 (WEEK 24)	2010-09-03	12:30	Plasma level Aβ1-40	04AUG2011	164.75		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V5 (WEEK 36)	2010-12-02	12:50	Plasma level Aβ1-40	04AUG2011	173.00		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-03-14	11:00	Plasma level Aβ1-40	04AUG2011	122.52		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.18		g/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	030	8	V6 (WEEK 52)	2011-03-14	14:15	CSF level Aβ1-40	11AUG2011	6413.80	YES	
						CSF level Aβ1-42	11AUG2011	707.84	YES	
						CSF level Phospho Tau	11AUG2011	97.95	YES	+
						CSF level Tau protein	11AUG2011	763.93	YES	+
			V7 (WEEK 56)	2011-04-11	11:30	Plasma level Aβ1-40	04AUG2011	146.68	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	032	8	V1 (WEEK 0)	2010-11-18	10:10	Plasma level Aβ1-40	28FEB2012	102.43	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.19		
							27FEB2012	0.19	YES	
						CSF level Aβ1-40	27FEB2012	6778.10	YES	
						CSF level Aβ1-42	27FEB2012	1192.80	YES	
						CSF level Phospho Tau	27FEB2012	55.72	YES	
						CSF level Tau protein	27FEB2012	419.64	YES	
			V3 (WEEK 12)	2011-02-07	12:23	Plasma level Aβ1-40	28FEB2012	109.60	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	033	9	V1 (WEEK 0)	2009-11-04	8:00	Plasma level Aβ1-40	06AUG2010	83.93		
							02SEP2011	112.44	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	030	8	V6 (WEEK 52)	2011-03-14	14:15	CSF level Aβ1-40	11AUG2011	6413.80		pg/mL
						CSF level Aβ1-42	11AUG2011	707.84		pg/mL
						CSF level Phospho Tau	11AUG2011	97.95	< 61	pg/mL
						CSF level Tau protein	11AUG2011	763.93	116 - 360	ng/L
			V7 (WEEK 56)	2011-04-11	11:30	Plasma level Aβ1-40	04AUG2011	146.68		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	032	8	V1 (WEEK 0)	2010-11-18	10:10	Plasma level Aβ1-40	28FEB2012	102.43		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.19	0.10 - 0.3	g/L
							27FEB2012	0.19	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	6778.10		pg/mL
						CSF level Aβ1-42	27FEB2012	1192.80		pg/mL
						CSF level Phospho Tau	27FEB2012	55.72	< 61	pg/mL
						CSF level Tau protein	27FEB2012	419.64	170 - 512	ng/L
			V3 (WEEK 12)	2011-02-07	12:23	Plasma level Aβ1-40	28FEB2012	109.60		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	033	9	V1 (WEEK 0)	2009-11-04	8:00	Plasma level Aβ1-40	06AUG2010	83.93		pg/mL
							02SEP2011	112.44		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	033	9	V1 (WEEK 0)	2009-11-04	8:00 11:20	Plasma level Aβ1-42	02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.23	YES	
						CSF level Aβ1-40	11AUG2010	6168.05		
							01SEP2011	7634.00	YES	
						CSF level Aβ1-42	11AUG2010	727.24		
							01SEP2011	836.99	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	91.53		+
							01SEP2011	73.84	YES	+
			V3 (WEEK 12)	2010-01-20	9:05	CSF level Tau protein	11AUG2010	794.79		+
							01SEP2011	438.38	YES	+
						Plasma level Aβ1-40	06AUG2010	83.12		
							02SEP2011	119.77	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
			V4 (WEEK 24)	2010-04-21	9:30	Plasma level Aβ1-40	06AUG2010	170.18		
							02SEP2011	225.70	YES	
						Plasma level Aβ1-42	06AUG2010	30.01		
			V5 (WEEK 36)	2010-07-22	8:30		02SEP2011	84.56	YES	
						Plasma level Aβ1-40	06AUG2010	157.36		
							02SEP2011	274.64	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	033	9	V1 (WEEK 0)	2009-11-04	8:00 11:20	Plasma level Aβ1-42	02SEP2011	<29.00	0.10 - 0.3	pg/mL
						Albumin (CSF)	02SEP2011	0.23		g/L
						CSF level Aβ1-40	11AUG2010	6168.05		pg/mL
							01SEP2011	7634.00		pg/mL
						CSF level Aβ1-42	11AUG2010	727.24		pg/mL
							01SEP2011	836.99		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	91.53		pg/mL
							01SEP2011	73.84		pg/mL
						CSF level Tau protein	11AUG2010	794.79		ng/L
			V3 (WEEK 12)	2010-01-20	9:05		01SEP2011	438.38	116 - 360	ng/L
						Plasma level Aβ1-40	06AUG2010	83.12		pg/mL
							02SEP2011	119.77		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V4 (WEEK 24)	2010-04-21	9:30		02SEP2011	<29.00		pg/mL
						Plasma level Aβ1-40	06AUG2010	170.18		pg/mL
							02SEP2011	225.70		pg/mL
						Plasma level Aβ1-42	06AUG2010	30.01		pg/mL
			V5 (WEEK 36)	2010-07-22	8:30		02SEP2011	84.56		pg/mL
						Plasma level Aβ1-40	06AUG2010	157.36		pg/mL
							02SEP2011	274.64		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	033	9	V5 (WEEK 36)	2010-07-22	8:30	Plasma level Aβ1-42	06AUG2010	41.25		
			V6 (WEEK 52)	2010-11-10	8:30	Plasma level Aβ1-40	02SEP2011	105.39	YES	
						Plasma level Aβ1-42	04AUG2011	116.78	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.21	YES	
						CSF level Aβ1-40	11AUG2011	8076.70	YES	
						CSF level Aβ1-42	11AUG2011	463.22	YES	
						CSF level Phospho Tau	11AUG2011	64.74	YES	+
						CSF level Tau protein	11AUG2011	381.50	YES	+
			V7 (WEEK 56)	2010-12-06	8:45	Plasma level Aβ1-40	04AUG2011	180.28	YES	
						Plasma level Aβ1-42	04AUG2011	94.09	YES	
	042	12	V1 (WEEK 0)	2010-01-14	9:15	Plasma level Aβ1-40	06AUG2010	69.54		
							01SEP2011	113.88	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
				2010-01-20	10:30		01SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.32	YES	+
						CSF level Aβ1-40	11AUG2010	4877.85		
							11AUG2011	5225.70	YES	
						CSF level Aβ1-42	11AUG2010	761.21		
							11AUG2011	679.36	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	033	9	V5 (WEEK 36)	2010-07-22	8:30	Plasma level Aβ1-42	06AUG2010	41.25		pg/mL
							02SEP2011	105.39		pg/mL
			V6 (WEEK 52)	2010-11-10	8:30	Plasma level Aβ1-40	04AUG2011	116.78		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.21	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	8076.70		pg/mL
						CSF level Aβ1-42	11AUG2011	463.22		pg/mL
						CSF level Phospho Tau	11AUG2011	64.74	< 61	pg/mL
						CSF level Tau protein	11AUG2011	381.50	116 - 360	ng/L
					8:45	Plasma level Aβ1-40	04AUG2011	180.28		pg/mL
						Plasma level Aβ1-42	04AUG2011	94.09		pg/mL
	042	12	V1 (WEEK 0)	2010-01-14	9:15	Plasma level Aβ1-40	06AUG2010	69.54		pg/mL
							01SEP2011	113.88		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							01SEP2011	<29.00		pg/mL
				2010-01-20	10:30	Albumin (CSF)	02SEP2011	0.32	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	4877.85		pg/mL
							11AUG2011	5225.70		pg/mL
						CSF level Aβ1-42	11AUG2010	761.21		pg/mL
							11AUG2011	679.36		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	042	12	V1 (WEEK 0)	2010-01-20	10:30	CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	81.77		+
							11AUG2011	66.65	YES	+
						CSF level Tau protein	11AUG2010	849.40		+
							11AUG2011	464.80	YES	
			V3 (WEEK 12)	2010-05-19	8:30	Plasma level Aβ1-40	06AUG2010	67.03		
							01SEP2011	99.79		
						Plasma level Aβ1-42	06AUG2010	<29.00		
			V4 (WEEK 24)	2010-06-30	8:45		01SEP2011	<29.00		
						Plasma level Aβ1-40	06AUG2010	39.76		
							01SEP2011	58.99		
						Plasma level Aβ1-42	06AUG2010	<29.00		
							01SEP2011	<29.00		
			V5 (WEEK 36)	2010-09-22	8:30	Plasma level Aβ1-40	24AUG2011	102.44	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-01-12	8:30	Plasma level Aβ1-40	24AUG2011	103.48	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V7 (WEEK 56)	2011-02-08	8:40	Plasma level Aβ1-40	24AUG2011	120.01	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
	043	12	V1 (WEEK 0)	2009-11-18	9:30	Plasma level Aβ1-40	06AUG2010	93.80	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	042	12	V1 (WEEK 0)	2010-01-20	10:30	CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	81.77	< 61	pg/mL
							11AUG2011	66.65	< 61	pg/mL
						CSF level Tau protein	11AUG2010	849.40	170 - 512	ng/L
							11AUG2011	464.80	170 - 512	ng/L
			V3 (WEEK 12)	2010-05-19	8:30	Plasma level Aβ1-40	06AUG2010	67.03		pg/mL
							01SEP2011	99.79		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							01SEP2011	<29.00		pg/mL
			V4 (WEEK 24)	2010-06-30	8:45	Plasma level Aβ1-40	06AUG2010	39.76		pg/mL
							01SEP2011	58.99		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							01SEP2011	<29.00		pg/mL
			V5 (WEEK 36)	2010-09-22	8:30	Plasma level Aβ1-40	24AUG2011	102.44		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-01-12	8:30	Plasma level Aβ1-40	24AUG2011	103.48		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
			V7 (WEEK 56)	2011-02-08	8:40	Plasma level Aβ1-40	24AUG2011	120.01		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
	043	12	V1 (WEEK 0)	2009-11-18	9:30	Plasma level Aβ1-40	06AUG2010	93.80		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	043	12	V1 (WEEK 0)	2009-11-18	9:30	Plasma level Aβ1-42	06AUG2010	<29.00	YES	+
					14:00	Albumin (CSF)	02SEP2011	0.36	YES	
						CSF level Aβ1-40	11AUG2010	6298.95	YES	
						CSF level Aβ1-42	11AUG2010	934.24	YES	
						CSF level F2-Isoprostane	11AUG2010	76.44	YES	
						CSF level Phospho Tau	11AUG2010	56.13	YES	
						CSF level Tau protein	11AUG2010	403.05	YES	
			V3 (WEEK 12)	2010-02-10	9:30	Plasma level Aβ1-40	06AUG2010	107.55	YES	+
			V4 (WEEK 24)	2010-05-12	9:00	Plasma level Aβ1-42	06AUG2010	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	116.99	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
	046	11	V1 (WEEK 0)	2010-01-11	9:45	Plasma level Aβ1-40	06AUG2010	201.58		++
							02SEP2011	263.33	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	48.56	YES	
							02SEP2011	0.45	YES	
					13:30	Albumin (CSF)	02SEP2011	0.45	YES	
						CSF level Aβ1-40	11AUG2010	6172.10		
							11AUG2011	6086.60	YES	
						CSF level Aβ1-42	11AUG2010	613.05		
							11AUG2011	661.56	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	043	12	V1 (WEEK 0)	2009-11-18	9:30	Plasma level Aβ1-42	06AUG2010	<29.00	0.10 - 0.3	pg/mL
					14:00	Albumin (CSF)	02SEP2011	0.36		g/L
						CSF level Aβ1-40	11AUG2010	6298.95		pg/mL
						CSF level Aβ1-42	11AUG2010	934.24		pg/mL
						CSF level F2-Isoprostane	11AUG2010	76.44		pg/mL
						CSF level Phospho Tau	11AUG2010	56.13		pg/mL
			V3 (WEEK 12)	2010-02-10	9:30	CSF level Tau protein	11AUG2010	403.05	< 61 116 - 360	ng/L
						Plasma level Aβ1-40	06AUG2010	107.55		pg/mL
			V4 (WEEK 24)	2010-05-12	9:00	Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
						Plasma level Aβ1-40	06AUG2010	116.99		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V1 (WEEK 0)	2010-01-11	9:45	Plasma level Aβ1-40	06AUG2010	201.58	0.10 - 0.3	pg/mL
							02SEP2011	263.33		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	48.56		pg/mL
					13:30	Albumin (CSF)	02SEP2011	0.45		g/L
							11AUG2010	6172.10		pg/mL
						CSF level Aβ1-40	11AUG2011	6086.60		pg/mL
							11AUG2010	613.05		pg/mL
						CSF level Aβ1-42	11AUG2011	661.56		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	046	11	V1 (WEEK 0)	2010-01-11	13:30	CSF level F2-Isoprostane	11AUG2010	59.74	YES	
						CSF level Phospho Tau	11AUG2010	118.93		+
							11AUG2011	96.18	YES	+
						CSF level Tau protein	11AUG2010	>1200		+
							11AUG2011	1065.30	YES	+
			V4 (WEEK 24)	2010-07-07	9:30	Plasma level Aβ1-40	06AUG2010	313.97		
							02SEP2011	335.92	YES	
						Plasma level Aβ1-42	06AUG2010	34.25		
							02SEP2011	63.71	YES	
			V5 (WEEK 36)	2010-09-22	11:40	Plasma level Aβ1-40	04AUG2011	210.03	YES	
						Plasma level Aβ1-42	04AUG2011	32.34	YES	
			V6 (WEEK 52)	2011-01-12	8:00	Plasma level Aβ1-40	04AUG2011	165.93	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.20	YES	
						CSF level Aβ1-40	11AUG2011	7184.20	YES	
						CSF level Aβ1-42	11AUG2011	787.57	YES	
						CSF level Phospho Tau	11AUG2011	95.13	YES	+
						CSF level Tau protein	11AUG2011	814.89	YES	+
			V7 (WEEK 56)	2011-02-07	8:15	Plasma level Aβ1-40	04AUG2011	177.99	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	046	11	V1 (WEEK 0)	2010-01-11	13:30	CSF level F2-Isoprostane	11AUG2010	59.74		pg/mL
						CSF level Phospho Tau	11AUG2010	118.93	< 61	pg/mL
							11AUG2011	96.18	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	170 - 512	ng/L
							11AUG2011	1065.30	170 - 512	ng/L
			V4 (WEEK 24)	2010-07-07	9:30	Plasma level Aβ1-40	06AUG2010	313.97		pg/mL
							02SEP2011	335.92		pg/mL
						Plasma level Aβ1-42	06AUG2010	34.25		pg/mL
							02SEP2011	63.71		pg/mL
			V5 (WEEK 36)	2010-09-22	11:40	Plasma level Aβ1-40	04AUG2011	210.03		pg/mL
						Plasma level Aβ1-42	04AUG2011	32.34		pg/mL
			V6 (WEEK 52)	2011-01-12	8:00	Plasma level Aβ1-40	04AUG2011	165.93		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.20	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	7184.20		pg/mL
						CSF level Aβ1-42	11AUG2011	787.57		pg/mL
						CSF level Phospho Tau	11AUG2011	95.13	< 61	pg/mL
						CSF level Tau protein	11AUG2011	814.89	170 - 512	ng/L
			V7 (WEEK 56)	2011-02-07	8:15	Plasma level Aβ1-40	04AUG2011	177.99		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	048	11	V1 (WEEK 0)	2010-11-22	10:30	Plasma level Aβ1-40	28FEB2012	88.53	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					12:30	Albumin (CSF)	02SEP2011	0.27		
							27FEB2012	0.32	YES	+
						CSF level Aβ1-40	27FEB2012	10419.00	YES	
						CSF level Aβ1-42	27FEB2012	1094.60	YES	
						CSF level Phospho Tau	27FEB2012	82.06	YES	+
						CSF level Tau protein	27FEB2012	574.87	YES	+
			V3 (WEEK 12)	2011-02-15	11:00	Plasma level Aβ1-40	28FEB2012	92.55	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-05-16	10:30	Plasma level Aβ1-40	28FEB2012	91.50	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-07-26	10:40	Plasma level Aβ1-40	28FEB2012	97.39	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-11-16	10:00	Plasma level Aβ1-40	28FEB2012	89.46	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					13:00	Albumin (CSF)	27FEB2012	0.32	YES	+
						CSF level Aβ1-40	27FEB2012	10437.00	YES	
						CSF level Aβ1-42	27FEB2012	1102.90	YES	
						CSF level Phospho Tau	27FEB2012	79.72	YES	+
						CSF level Tau protein	27FEB2012	644.91	YES	+

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	048	11	V1 (WEEK 0)	2010-11-22	10:30	Plasma level Aβ1-40	28FEB2012	88.53		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					12:30	Albumin (CSF)	02SEP2011	0.27	0.10 - 0.3	g/L
							27FEB2012	0.32	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	10419.00		pg/mL
						CSF level Aβ1-42	27FEB2012	1094.60		pg/mL
						CSF level Phospho Tau	27FEB2012	82.06	< 61	pg/mL
						CSF level Tau protein	27FEB2012	574.87	170 - 512	ng/L
			V3 (WEEK 12)	2011-02-15	11:00	Plasma level Aβ1-40	28FEB2012	92.55		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-05-16	10:30	Plasma level Aβ1-40	28FEB2012	91.50		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-07-26	10:40	Plasma level Aβ1-40	28FEB2012	97.39		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-11-16	10:00	Plasma level Aβ1-40	28FEB2012	89.46		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					13:00	Albumin (CSF)	27FEB2012	0.32	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	10437.00		pg/mL
						CSF level Aβ1-42	27FEB2012	1102.90		pg/mL
						CSF level Phospho Tau	27FEB2012	79.72	< 61	pg/mL
						CSF level Tau protein	27FEB2012	644.91	170 - 512	ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	048	11	V7 (WEEK 56)	2011-12-21	11:20	Plasma level Aβ1-40	28FEB2012	98.05	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	050	21	V1 (WEEK 0)	2010-10-27	11:45	Plasma level Aβ1-40	28FEB2012	165.31	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					14:00	Albumin (CSF)	27FEB2012	0.14	YES	
						CSF level Aβ1-40	27FEB2012	7846.60	YES	
						CSF level Aβ1-42	27FEB2012	906.84	YES	
						CSF level Phospho Tau	27FEB2012	63.02	YES	+
						CSF level Tau protein	27FEB2012	534.93	YES	+
			V4 (WEEK 24)	2011-04-11	11:20	Plasma level Aβ1-40	28FEB2012	96.87	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-07-04	11:50	Plasma level Aβ1-40	28FEB2012	215.45	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-10-24	9:00	Plasma level Aβ1-40	28FEB2012	149.31	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					11:15	Albumin (CSF)	27FEB2012	0.15	YES	
						CSF level Aβ1-40	27FEB2012	6647.80	YES	
						CSF level Aβ1-42	27FEB2012	782.62	YES	
						CSF level Phospho Tau	27FEB2012	62.87	YES	+
						CSF level Tau protein	27FEB2012	487.84	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	048	11	V7 (WEEK 56)	2011-12-21	11:20	Plasma level Aβ1-40	28FEB2012	98.05		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	050	21	V1 (WEEK 0)	2010-10-27	11:45	Plasma level Aβ1-40	28FEB2012	165.31		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					14:00	Albumin (CSF)	27FEB2012	0.14	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	7846.60		pg/mL
						CSF level Aβ1-42	27FEB2012	906.84		pg/mL
						CSF level Phospho Tau	27FEB2012	63.02	< 61	pg/mL
						CSF level Tau protein	27FEB2012	534.93	170 - 512	ng/L
			V4 (WEEK 24)	2011-04-11	11:20	Plasma level Aβ1-40	28FEB2012	96.87		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-07-04	11:50	Plasma level Aβ1-40	28FEB2012	215.45		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-10-24	9:00	Plasma level Aβ1-40	28FEB2012	149.31		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					11:15	Albumin (CSF)	27FEB2012	0.15	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	6647.80		pg/mL
						CSF level Aβ1-42	27FEB2012	782.62		pg/mL
						CSF level Phospho Tau	27FEB2012	62.87	< 61	pg/mL
						CSF level Tau protein	27FEB2012	487.84	170 - 512	ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Comment
				Date	Time				
ACI-91	048	11	V7 (WEEK 56)	2011-12-21	11:20	Plasma level Aβ1-40	28FEB2012	98.05	
						Plasma level Aβ1-42	28FEB2012	<29.00	
	050	21	V1 (WEEK 0)	2010-10-27	11:45	Plasma level Aβ1-40	28FEB2012	165.31	
						Plasma level Aβ1-42	28FEB2012	<29.00	
					14:00	Albumin (CSF)	27FEB2012	0.14	
						CSF level Aβ1-40	27FEB2012	7846.60	
						CSF level Aβ1-42	27FEB2012	906.84	
						CSF level Phospho Tau	27FEB2012	63.02	
						CSF level Tau protein	27FEB2012	534.93	
			V4 (WEEK 24)	2011-04-11	11:20	Plasma level Aβ1-40	28FEB2012	96.87	HEMOLYTIC
						Plasma level Aβ1-42	28FEB2012	<29.00	HEMOLYTIC
			V5 (WEEK 36)	2011-07-04	11:50	Plasma level Aβ1-40	28FEB2012	215.45	
						Plasma level Aβ1-42	28FEB2012	<29.00	
			V6 (WEEK 52)	2011-10-24	9:00	Plasma level Aβ1-40	28FEB2012	149.31	
						Plasma level Aβ1-42	28FEB2012	<29.00	
					11:15	Albumin (CSF)	27FEB2012	0.15	
						CSF level Aβ1-40	27FEB2012	6647.80	
						CSF level Aβ1-42	27FEB2012	782.62	
						CSF level Phospho Tau	27FEB2012	62.87	
						CSF level Tau protein	27FEB2012	487.84	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	050	21	V7 (WEEK 56)	2011-11-21	8:51	Plasma level Aβ1-40	28FEB2012	147.03	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	052	21	V1 (WEEK 0)	2010-10-28	8:15	Plasma level Aβ1-40	28FEB2012	145.88	YES	
						Plasma level Aβ1-42	28FEB2012	572.36	YES	
					11:15	Albumin (CSF)	27FEB2012	0.09	YES	-
						CSF level Aβ1-40	27FEB2012	6393.00	YES	
						CSF level Aβ1-42	27FEB2012	529.29	YES	
						CSF level Phospho Tau	27FEB2012	54.28	YES	
						CSF level Tau protein	27FEB2012	426.57	YES	
			V4 (WEEK 24)	2011-04-11	10:45	Plasma level Aβ1-40	28FEB2012	98.62	YES	
						Plasma level Aβ1-42	28FEB2012	550.04	YES	
			V5 (WEEK 36)	2011-07-04	9:24	Plasma level Aβ1-40	28FEB2012	237.70	YES	
						Plasma level Aβ1-42	28FEB2012	625.18	YES	
			V6 (WEEK 52)	2011-10-24	12:15	Plasma level Aβ1-40	28FEB2012	135.78	YES	
						Plasma level Aβ1-42	28FEB2012	448.26	YES	
					14:55	Albumin (CSF)	27FEB2012	0.10	YES	-
						CSF level Aβ1-40	27FEB2012	6548.50	YES	
						CSF level Aβ1-42	27FEB2012	676.30	YES	
						CSF level Phospho Tau	27FEB2012	47.52	YES	
						CSF level Tau protein	27FEB2012	425.57	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	050	21	V7 (WEEK 56)	2011-11-21	8:51	Plasma level Aβ1-40	28FEB2012	147.03		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	052	21	V1 (WEEK 0)	2010-10-28	8:15	Plasma level Aβ1-40	28FEB2012	145.88		pg/mL
						Plasma level Aβ1-42	28FEB2012	572.36		pg/mL
					11:15	Albumin (CSF)	27FEB2012	0.09	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	6393.00		pg/mL
						CSF level Aβ1-42	27FEB2012	529.29		pg/mL
						CSF level Phospho Tau	27FEB2012	54.28	< 61	pg/mL
						CSF level Tau protein	27FEB2012	426.57	170 - 512	ng/L
			V4 (WEEK 24)	2011-04-11	10:45	Plasma level Aβ1-40	28FEB2012	98.62		pg/mL
						Plasma level Aβ1-42	28FEB2012	550.04		pg/mL
			V5 (WEEK 36)	2011-07-04	9:24	Plasma level Aβ1-40	28FEB2012	237.70		pg/mL
						Plasma level Aβ1-42	28FEB2012	625.18		pg/mL
			V6 (WEEK 52)	2011-10-24	12:15	Plasma level Aβ1-40	28FEB2012	135.78		pg/mL
						Plasma level Aβ1-42	28FEB2012	448.26		pg/mL
					14:55	Albumin (CSF)	27FEB2012	0.10	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	6548.50		pg/mL
						CSF level Aβ1-42	27FEB2012	676.30		pg/mL
						CSF level Phospho Tau	27FEB2012	47.52	< 61	pg/mL
						CSF level Tau protein	27FEB2012	425.57	170 - 512	ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Comment
				Date	Time				
ACI-91	050	21	V7 (WEEK 56)	2011-11-21	8:51	Plasma level Aβ1-40	28FEB2012	147.03	
						Plasma level Aβ1-42	28FEB2012	<29.00	
	052	21	V1 (WEEK 0)	2010-10-28	8:15	Plasma level Aβ1-40	28FEB2012	145.88	
						Plasma level Aβ1-42	28FEB2012	572.36	
					11:15	Albumin (CSF)	27FEB2012	0.09	
						CSF level Aβ1-40	27FEB2012	6393.00	
						CSF level Aβ1-42	27FEB2012	529.29	
						CSF level Phospho Tau	27FEB2012	54.28	
						CSF level Tau protein	27FEB2012	426.57	
			V4 (WEEK 24)	2011-04-11	10:45	Plasma level Aβ1-40	28FEB2012	98.62	HEMOLYTIC
						Plasma level Aβ1-42	28FEB2012	550.04	HEMOLYTIC
			V5 (WEEK 36)	2011-07-04	9:24	Plasma level Aβ1-40	28FEB2012	237.70	
						Plasma level Aβ1-42	28FEB2012	625.18	
			V6 (WEEK 52)	2011-10-24	12:15	Plasma level Aβ1-40	28FEB2012	135.78	
						Plasma level Aβ1-42	28FEB2012	448.26	
					14:55	Albumin (CSF)	27FEB2012	0.10	
						CSF level Aβ1-40	27FEB2012	6548.50	
						CSF level Aβ1-42	27FEB2012	676.30	
						CSF level Phospho Tau	27FEB2012	47.52	
						CSF level Tau protein	27FEB2012	425.57	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	052	21	V7 (WEEK 56)	2011-11-21	9:46	Plasma level Aβ1-40	28FEB2012	95.34	YES	
						Plasma level Aβ1-42	28FEB2012	370.34	YES	
	055	5	V1 (WEEK 0)	2010-03-29	9:30	Plasma level Aβ1-40	06AUG2010	156.16	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					13:15	Albumin (CSF)	02SEP2011	0.24	YES	
						CSF level Aβ1-40	11AUG2010	6061.90	YES	
						CSF level Aβ1-42	11AUG2010	580.50	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	144.11	YES	+
						CSF level Tau protein	11AUG2010	>1200	YES	+
						Plasma level Aβ1-40	06AUG2010	129.61	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
			V6 (WEEK 52)	2010-04-27	9:15					
	057	1	V1 (WEEK 0)	2010-08-19	11:10	Plasma level Aβ1-40	28FEB2012	119.69	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					13:40	Albumin (CSF)	02SEP2011	0.15		
							27FEB2012	0.14	YES	
						CSF level Aβ1-40	27FEB2012	8130.50	YES	
						CSF level Aβ1-42	27FEB2012	2067.90	YES	
						CSF level Phospho Tau	27FEB2012	53.13	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	052	21	V7 (WEEK 56)	2011-11-21	9:46	Plasma level Aβ1-40	28FEB2012	95.34		pg/mL
						Plasma level Aβ1-42	28FEB2012	370.34		pg/mL
	055	5	V1 (WEEK 0)	2010-03-29	9:30	Plasma level Aβ1-40	06AUG2010	156.16		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.24	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	6061.90		pg/mL
						CSF level Aβ1-42	11AUG2010	580.50		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	144.11	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	170 - 512	ng/L
			V6 (WEEK 52)	2010-04-27	9:15	Plasma level Aβ1-40	06AUG2010	129.61		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
	057	1	V1 (WEEK 0)	2010-08-19	11:10	Plasma level Aβ1-40	28FEB2012	119.69		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.15	0.10 - 0.3	g/L
							27FEB2012	0.14	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	8130.50		pg/mL
						CSF level Aβ1-42	27FEB2012	2067.90		pg/mL
						CSF level Phospho Tau	27FEB2012	53.13	< 61	pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	057	1	V1 (WEEK 0)	2010-08-19	13:40	CSF level Tau protein	27FEB2012	568.00	YES	+
			V3 (WEEK 12)	2010-11-08	9:45	Plasma level Aβ1-40	28FEB2012	106.28	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-02-04	9:35	Plasma level Aβ1-40	28FEB2012	110.80	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	066	16	V1 (WEEK 0)	2010-09-09	8:45	Albumin (CSF)	27FEB2012	0.23	YES	+
						CSF level Aβ1-40	27FEB2012	7673.80	YES	
						CSF level Aβ1-42	27FEB2012	1044.40	YES	
						CSF level Phospho Tau	27FEB2012	71.25	YES	
						CSF level Tau protein	27FEB2012	501.94	YES	
					9:25	Plasma level Aβ1-40	28FEB2012	127.54	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V3 (WEEK 12)	2010-11-30	9:15	Plasma level Aβ1-40	28FEB2012	153.43	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	067	16	V1 (WEEK 0)	2010-11-18	8:15	Albumin (CSF)	27FEB2012	0.29	YES	
						CSF level Aβ1-40	27FEB2012	6034.10	YES	
						CSF level Aβ1-42	27FEB2012	1330.60	YES	
						CSF level Phospho Tau	27FEB2012	<31.00	YES	
						CSF level Tau protein	27FEB2012	142.95	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	057	1	V1 (WEEK 0)	2010-08-19	13:40	CSF level Tau protein	27FEB2012	568.00	116 - 360	ng/L
			V3 (WEEK 12)	2010-11-08	9:45	Plasma level Aβ1-40	28FEB2012	106.28		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-02-04	9:35	Plasma level Aβ1-40	28FEB2012	110.80		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	066	16	V1 (WEEK 0)	2010-09-09	8:45	Albumin (CSF)	27FEB2012	0.23	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	7673.80		pg/mL
						CSF level Aβ1-42	27FEB2012	1044.40		pg/mL
						CSF level Phospho Tau	27FEB2012	71.25		pg/mL
			V3 (WEEK 12)	2010-11-30	9:15	CSF level Tau protein	27FEB2012	501.94	170 - 512	ng/L
						Plasma level Aβ1-40	28FEB2012	127.54		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	153.43		pg/mL
	067	16	V1 (WEEK 0)	2010-11-18	8:15	Albumin (CSF)	27FEB2012	0.29	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	6034.10		pg/mL
						CSF level Aβ1-42	27FEB2012	1330.60		pg/mL
						CSF level Phospho Tau	27FEB2012	<31.00		pg/mL
						CSF level Tau protein	27FEB2012	142.95		ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	067	16	V1 (WEEK 0)	2010-11-18	8:30	Plasma level Aβ1-40	28FEB2012	133.32	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	071	18	V1 (WEEK 0)	2010-11-09	11:00	Plasma level Aβ1-40	28FEB2012	88.67	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					15:05	Albumin (CSF)	02SEP2011	0.27		
							27FEB2012	0.28	YES	
						CSF level Aβ1-40	27FEB2012	8350.30	YES	
						CSF level Aβ1-42	27FEB2012	976.07	YES	
						CSF level Phospho Tau	27FEB2012	108.54	YES	+
						CSF level Tau protein	27FEB2012	1287.90	YES	+
			V3 (WEEK 12)	2011-02-03	10:07	Plasma level Aβ1-40	28FEB2012	88.01	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-05-04	9:35	Plasma level Aβ1-40	28FEB2012	119.93	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-07-19	9:41	Plasma level Aβ1-40	28FEB2012	112.63	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-11-17	11:02	Plasma level Aβ1-40	28FEB2012	93.13	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2011-12-05	12:01	Plasma level Aβ1-40	28FEB2012	94.19	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	067	16	V1 (WEEK 0)	2010-11-18	8:30	Plasma level Aβ1-40	28FEB2012	133.32		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	071	18	V1 (WEEK 0)	2010-11-09	11:00	Plasma level Aβ1-40	28FEB2012	88.67		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					15:05	Albumin (CSF)	02SEP2011	0.27	0.10 - 0.3	g/L
							27FEB2012	0.28	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	8350.30		pg/mL
						CSF level Aβ1-42	27FEB2012	976.07		pg/mL
						CSF level Phospho Tau	27FEB2012	108.54	< 61	pg/mL
						CSF level Tau protein	27FEB2012	1287.90	116 - 360	ng/L
			V3 (WEEK 12)	2011-02-03	10:07	Plasma level Aβ1-40	28FEB2012	88.01		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-05-04	9:35	Plasma level Aβ1-40	28FEB2012	119.93		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-07-19	9:41	Plasma level Aβ1-40	28FEB2012	112.63		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-11-17	11:02	Plasma level Aβ1-40	28FEB2012	93.13		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2011-12-05	12:01	Plasma level Aβ1-40	28FEB2012	94.19		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	080	13	V1 (WEEK 0)	2010-11-18	12:30	Plasma level Aβ1-40	28FEB2012	107.95	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					2010-11-19	14:00	Albumin (CSF)	02SEP2011	0.37	+
								27FEB2012	0.41	+
				V3 (WEEK 12)	2011-02-09	CSF level Aβ1-40	27FEB2012	9469.90	YES	
						CSF level Aβ1-42	27FEB2012	644.75	YES	
						CSF level Phospho Tau	27FEB2012	153.28	YES	+
						CSF level Tau protein	27FEB2012	1335.10	YES	+
						Plasma level Aβ1-40	28FEB2012	94.56	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					13:40	Albumin (CSF)	02SEP2011	0.39		+
							27FEB2012	0.39	YES	+
						CSF level Aβ1-40	27FEB2012	8433.10	YES	
						CSF level Aβ1-42	27FEB2012	596.68	YES	
						CSF level Phospho Tau	27FEB2012	146.70	YES	+
						CSF level Tau protein	27FEB2012	1483.90	YES	+
	081	17	V1 (WEEK 0)	2010-10-14	10:00	Plasma level Aβ1-40	28FEB2012	109.45	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					13:30	Albumin (CSF)	02SEP2011	0.31		+
							27FEB2012	0.36	YES	+

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling			Date of entry (MLM)	Result	Reference range	Unit	
				Date	Time	Parameter					
ACI-91	080	13	V1 (WEEK 0)	2010-11-18	12:30	Plasma level Aβ1-40	28FEB2012	107.95		pg/mL	
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL	
				2010-11-19	14:00	Albumin (CSF)	02SEP2011	0.37	0.10 - 0.3	g/L	
							27FEB2012	0.41	0.10 - 0.3	g/L	
				2011-02-09	11:30	CSF level Aβ1-40	27FEB2012	9469.90		pg/mL	
						CSF level Aβ1-42	27FEB2012	644.75		pg/mL	
						CSF level Phospho Tau	27FEB2012	153.28	< 61	pg/mL	
						CSF level Tau protein	27FEB2012	1335.10	170 - 512	ng/L	
			V3 (WEEK 12)			11:30	Plasma level Aβ1-40	28FEB2012	94.56		pg/mL
							Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			2011-02-09	13:40	Albumin (CSF)	02SEP2011	0.39	0.10 - 0.3	g/L		
						27FEB2012	0.39	0.10 - 0.3	g/L		
					CSF level Aβ1-40	27FEB2012	8433.10		pg/mL		
					CSF level Aβ1-42	27FEB2012	596.68		pg/mL		
					CSF level Phospho Tau	27FEB2012	146.70	< 61	pg/mL		
					CSF level Tau protein	27FEB2012	1483.90	170 - 512	ng/L		
081	17	V1 (WEEK 0)			2010-10-14	10:00	Plasma level Aβ1-40	28FEB2012	109.45		pg/mL
							Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
				13:30	Albumin (CSF)	02SEP2011	0.31	0.10 - 0.3	g/L		
						27FEB2012	0.36	0.10 - 0.3	q/L		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	081	17	V1 (WEEK 0)	2010-10-14	13:30	CSF level Aβ1-40	27FEB2012	5653.50	YES	
						CSF level Aβ1-42	27FEB2012	905.89	YES	
						CSF level Phospho Tau	27FEB2012	58.60	YES	
						CSF level Tau protein	27FEB2012	394.04	YES	
			V4 (WEEK 24)	2011-04-06	9:30	Plasma level Aβ1-40	28FEB2012	86.71	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-06-20	11:00	Plasma level Aβ1-40	28FEB2012	101.44	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2011-11-22	10:45	Plasma level Aβ1-40	28FEB2012	100.31	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	083	17	V1 (WEEK 0)	2010-11-10	9:25	Plasma level Aβ1-40	28FEB2012	Disturbing factors e.g. from diet or medication . Measurement not possible.		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	081	17	V1 (WEEK 0)	2010-10-14	13:30	CSF level Aβ1-40	27FEB2012	5653.50		pg/mL
						CSF level Aβ1-42	27FEB2012	905.89		pg/mL
						CSF level Phospho Tau	27FEB2012	58.60	< 61	pg/mL
						CSF level Tau protein	27FEB2012	394.04	170 - 512	ng/L
			V4 (WEEK 24)	2011-04-06	9:30	Plasma level Aβ1-40	28FEB2012	86.71		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-06-20	11:00	Plasma level Aβ1-40	28FEB2012	101.44		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2011-11-22	10:45	Plasma level Aβ1-40	28FEB2012	100.31		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	083	17	V1 (WEEK 0)	2010-11-10	9:25	Plasma level Aβ1-40	28FEB2012	Disturbing factors e.g. from diet or medication . Measurement not possible.		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	083	17	V1 (WEEK 0)	2010-11-10	9:25	Plasma level Aβ1-42	28FEB2012	Disturbing factors e.g. from diet or medication		
								. Measurement not possible.		
			V5 (WEEK 36)	2011-07-25	10:50	13:30 Albumin (CSF)	02SEP2011	0.06		-
							27FEB2012	0.07	YES	-
						CSF level Aβ1-40	27FEB2012	1588.10	YES	
						CSF level Aβ1-42	27FEB2012	<194.00	YES	
						CSF level Phospho Tau	27FEB2012	<31.00	YES	
						CSF level Tau protein	27FEB2012	89.82	YES	-
			V6 (WEEK 52)	2011-11-09	10:20	Plasma level Aβ1-40	28FEB2012	141.38	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	125.26	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
				2011-11-10	9:30	Albumin (CSF)	27FEB2012	0.12	YES	
						CSF level Aβ1-40	27FEB2012	4763.10	YES	

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	083	17	V1 (WEEK 0)	2010-11-10	9:25	Plasma level Aβ1-42	28FEB2012	Disturbing factors e.g. from diet or medication . Measurement not possible.		pg/mL
						Albumin (CSF)	02SEP2011	0.06	0.10 - 0.3	g/L
							27FEB2012	0.07	0.10 - 0.3	g/L
			V5 (WEEK 36)	2011-07-25	10:50	CSF level Aβ1-40	27FEB2012	1588.10		pg/mL
						CSF level Aβ1-42	27FEB2012	<194.00		pg/mL
						CSF level Phospho Tau	27FEB2012	<31.00	< 61	pg/mL
						CSF level Tau protein	27FEB2012	89.82	170 - 512	ng/L
						Plasma level Aβ1-40	28FEB2012	141.38		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-11-09	10:20	Plasma level Aβ1-40	28FEB2012	125.26		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	27FEB2012	0.12	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	4763.10		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	083	17	V6 (WEEK 52)	2011-11-10	9:30	CSF level Aβ1-42	27FEB2012	484.98	YES	+
						CSF level Phospho Tau	27FEB2012	69.95	YES	
						CSF level Tau protein	27FEB2012	468.36	YES	
			V7 (WEEK 56)	2011-12-06	10:20	Plasma level Aβ1-40	28FEB2012	133.35	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	087	16	V1 (WEEK 0)	2010-11-29	9:45	Albumin (CSF)	02SEP2011	0.28		+
							27FEB2012	0.29	YES	
						CSF level Aβ1-40	27FEB2012	11646.00	YES	
						CSF level Aβ1-42	27FEB2012	921.56	YES	
						CSF level Phospho Tau	27FEB2012	180.24	YES	
					10:10	CSF level Tau protein	27FEB2012	1832.60	YES	
						Plasma level Aβ1-40	28FEB2012	198.07	YES	
						Plasma level Aβ1-42	28FEB2012	82.88	YES	
			V3 (WEEK 12)	2011-02-17	9:35	Plasma level Aβ1-40	28FEB2012	118.47	YES	
						Plasma level Aβ1-42	28FEB2012	51.55	YES	
			V4 (WEEK 24)	2011-05-16	11:00	Plasma level Aβ1-40	28FEB2012	211.35	YES	
						Plasma level Aβ1-42	28FEB2012	93.74	YES	
			V5 (WEEK 36)	2011-08-10	10:20	Plasma level Aβ1-40	28FEB2012	244.86	YES	
						Plasma level Aβ1-42	28FEB2012	89.32	YES	
			V6 (WEEK 52)	2011-11-28	9:45	Albumin (CSF)	27FEB2012	0.30	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	083	17	V6 (WEEK 52)	2011-11-10	9:30	CSF level Aβ1-42	27FEB2012	484.98		pg/mL
						CSF level Phospho Tau	27FEB2012	69.95	< 61	pg/mL
						CSF level Tau protein	27FEB2012	468.36	170 - 512	ng/L
			V7 (WEEK 56)	2011-12-06	10:20	Plasma level Aβ1-40	28FEB2012	133.35		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	087	16	V1 (WEEK 0)	2010-11-29	9:45	Albumin (CSF)	02SEP2011	0.28	0.10 - 0.3	g/L
							27FEB2012	0.29	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	11646.00		pg/mL
						CSF level Aβ1-42	27FEB2012	921.56		pg/mL
						CSF level Phospho Tau	27FEB2012	180.24	< 61	pg/mL
					10:10	CSF level Tau protein	27FEB2012	1832.60	170 - 512	ng/L
						Plasma level Aβ1-40	28FEB2012	198.07		pg/mL
					9:35	Plasma level Aβ1-42	28FEB2012	82.88		pg/mL
						Plasma level Aβ1-40	28FEB2012	118.47		pg/mL
						Plasma level Aβ1-42	28FEB2012	51.55		pg/mL
			V4 (WEEK 24)	2011-05-16	11:00	Plasma level Aβ1-40	28FEB2012	211.35		pg/mL
						Plasma level Aβ1-42	28FEB2012	93.74		pg/mL
			V5 (WEEK 36)	2011-08-10	10:20	Plasma level Aβ1-40	28FEB2012	244.86		pg/mL
						Plasma level Aβ1-42	28FEB2012	89.32		pg/mL
			V6 (WEEK 52)	2011-11-28	9:45	Albumin (CSF)	27FEB2012	0.30	0.10 - 0.3	g/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Comment
				Date	Time				
ACI-91	083	17	V6 (WEEK 52)	2011-11-10	9:30	CSF level Aβ1-42	27FEB2012	484.98	
						CSF level Phospho Tau	27FEB2012	69.95	
						CSF level Tau protein	27FEB2012	468.36	
			V7 (WEEK 56)	2011-12-06	10:20	Plasma level Aβ1-40	28FEB2012	133.35	
						Plasma level Aβ1-42	28FEB2012	<29.00	
	087	16	V1 (WEEK 0)	2010-11-29	9:45	Albumin (CSF)	02SEP2011	0.28	
							27FEB2012	0.29	
						CSF level Aβ1-40	27FEB2012	11646.00	
						CSF level Aβ1-42	27FEB2012	921.56	
						CSF level Phospho Tau	27FEB2012	180.24	
					10:10	CSF level Tau protein	27FEB2012	1832.60	
						Plasma level Aβ1-40	28FEB2012	198.07	
						Plasma level Aβ1-42	28FEB2012	82.88	
						Plasma level Aβ1-40	28FEB2012	118.47	HEMOLYTIC
						Plasma level Aβ1-42	28FEB2012	51.55	HEMOLYTIC
			V4 (WEEK 24)	2011-05-16	11:00	Plasma level Aβ1-40	28FEB2012	211.35	
			V5 (WEEK 36)	2011-08-10	10:20	Plasma level Aβ1-42	28FEB2012	93.74	
						Plasma level Aβ1-40	28FEB2012	244.86	
			V6 (WEEK 52)	2011-11-28	9:45	Plasma level Aβ1-42	28FEB2012	89.32	
						Albumin (CSF)	27FEB2012	0.30	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	087	16	V6 (WEEK 52)	2011-11-28	9:45	CSF level Aβ1-40	27FEB2012	13104.00	YES	
						CSF level Aβ1-42	27FEB2012	864.69	YES	
						CSF level Phospho Tau	27FEB2012	168.93	YES	+
						CSF level Tau protein	27FEB2012	1536.30	YES	+
					10:15	Plasma level Aβ1-40	28FEB2012	301.80	YES	
						Plasma level Aβ1-42	28FEB2012	126.85	YES	
			V7 (WEEK 56)	2011-12-28	12:00	Plasma level Aβ1-40	28FEB2012	219.18	YES	
						Plasma level Aβ1-42	28FEB2012	86.15	YES	
	089	5	V1 (WEEK 0)	2010-11-16	12:00	Albumin (CSF)	02SEP2011	0.42		+
							27FEB2012	0.27	YES	
						CSF level Aβ1-40	27FEB2012	4988.30	YES	
						CSF level Aβ1-42	27FEB2012	809.26	YES	
						CSF level Phospho Tau	27FEB2012	46.14	YES	
						CSF level Tau protein	27FEB2012	314.62	YES	
						Plasma level Aβ1-40	28FEB2012	138.61	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V3 (WEEK 12)	2011-02-07	11:30	Plasma level Aβ1-40	28FEB2012	174.05	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-05-02	10:15	Plasma level Aβ1-40	28FEB2012	165.32	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	087	16	V6 (WEEK 52)	2011-11-28	9:45	CSF level Aβ1-40	27FEB2012	13104.00		pg/mL
						CSF level Aβ1-42	27FEB2012	864.69		pg/mL
						CSF level Phospho Tau	27FEB2012	168.93	< 61	pg/mL
						CSF level Tau protein	27FEB2012	1536.30	170 - 512	ng/L
					10:15	Plasma level Aβ1-40	28FEB2012	301.80		pg/mL
						Plasma level Aβ1-42	28FEB2012	126.85		pg/mL
			V7 (WEEK 56)	2011-12-28	12:00	Plasma level Aβ1-40	28FEB2012	219.18		pg/mL
						Plasma level Aβ1-42	28FEB2012	86.15		pg/mL
	089	5	V1 (WEEK 0)	2010-11-16	12:00	Albumin (CSF)	02SEP2011	0.42	0.10 - 0.3	g/L
							27FEB2012	0.27	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	4988.30		pg/mL
						CSF level Aβ1-42	27FEB2012	809.26		pg/mL
						CSF level Phospho Tau	27FEB2012	46.14	< 61	pg/mL
						CSF level Tau protein	27FEB2012	314.62	116 - 360	ng/L
						Plasma level Aβ1-40	28FEB2012	138.61		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V3 (WEEK 12)	2011-02-07	11:30	Plasma level Aβ1-40	28FEB2012	174.05		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-05-02	10:15	Plasma level Aβ1-40	28FEB2012	165.32		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	089	5	V5 (WEEK 36)	2011-07-25	12:00	Plasma level Aβ1-40	28FEB2012	135.93	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-11-14	12:30	Plasma level Aβ1-40	28FEB2012	145.08	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2011-12-14	13:00	Plasma level Aβ1-40	28FEB2012	121.39	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	093	17	V1 (WEEK 0)	2010-12-02	8:30 13:30	Plasma level Aβ1-40	28FEB2012	49.37	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.35		+
							27FEB2012	0.36	YES	+
						CSF level Aβ1-40	27FEB2012	6412.00	YES	
						CSF level Aβ1-42	27FEB2012	556.04	YES	
			V4 (WEEK 24)	2011-05-23	11:45	CSF level Phospho Tau	27FEB2012	112.20	YES	+
						CSF level Tau protein	27FEB2012	1094.80	YES	+
						Plasma level Aβ1-40	28FEB2012	113.22	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-08-16	10:30	Plasma level Aβ1-40	28FEB2012	107.42	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2011-12-28	10:15	Plasma level Aβ1-40	28FEB2012	126.51	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	089	5	V5 (WEEK 36)	2011-07-25	12:00	Plasma level Aβ1-40	28FEB2012	135.93		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-11-14	12:30	Plasma level Aβ1-40	28FEB2012	145.08		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2011-12-14	13:00	Plasma level Aβ1-40	28FEB2012	121.39		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	093	17	V1 (WEEK 0)	2010-12-02	8:30 13:30	Plasma level Aβ1-40	28FEB2012	49.37		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.35	0.10 - 0.3	g/L
							27FEB2012	0.36	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	6412.00		pg/mL
						CSF level Aβ1-42	27FEB2012	556.04		pg/mL
			V4 (WEEK 24)	2011-05-23	11:45	CSF level Phospho Tau	27FEB2012	112.20	< 61	pg/mL
						CSF level Tau protein	27FEB2012	1094.80	116 - 360	ng/L
						Plasma level Aβ1-40	28FEB2012	113.22		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-08-16	10:30	Plasma level Aβ1-40	28FEB2012	107.42		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2011-12-28	10:15	Plasma level Aβ1-40	28FEB2012	126.51		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
ACI-91	097	12	V1 (WEEK 0)	2010-11-17	8:30	Plasma level Aβ1-40	28FEB2012	116.18	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					12:00	Albumin (CSF)	02SEP2011	0.40		+
							27FEB2012	0.43	YES	+
						CSF level Aβ1-40	27FEB2012	5508.30	YES	
			V3 (WEEK 12)	2011-02-09	8:15	CSF level Aβ1-42	27FEB2012	727.99	YES	
						CSF level Phospho Tau	27FEB2012	56.43	YES	
						CSF level Tau protein	27FEB2012	438.76	YES	
						Plasma level Aβ1-40	28FEB2012	129.44	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
Placebo	001	1	V1 (WEEK 0)	2009-04-09	10:30	Plasma level Aβ1-40	04AUG2010	73.57	YES	
						Plasma level Aβ1-42	04AUG2010	<29.00	YES	
					11:15	Albumin (CSF)	02SEP2011	0.39	YES	+
						CSF level Aβ1-40	11AUG2010	5591.90	YES	
						CSF level Aβ1-42	11AUG2010	478.77	YES	
			V3 (WEEK 12)	2009-07-07	8:55	CSF level F2-Isoprostane	11AUG2010	57.61	YES	
						CSF level Phospho Tau	11AUG2010	194.82	YES	+
						CSF level Tau protein	11AUG2010	>1200	YES	+
						Plasma level Aβ1-40	06AUG2010	85.36	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
ACI-91	097	12	V1 (WEEK 0)	2010-11-17	8:30	Plasma level Aβ1-40	28FEB2012	116.18		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					12:00	Albumin (CSF)	02SEP2011	0.40	0.10 - 0.3	g/L
							27FEB2012	0.43	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	5508.30		pg/mL
			V3 (WEEK 12)	2011-02-09	8:15	CSF level Aβ1-42	27FEB2012	727.99		pg/mL
						CSF level Phospho Tau	27FEB2012	56.43	< 61	pg/mL
						CSF level Tau protein	27FEB2012	438.76	170 - 512	ng/L
						Plasma level Aβ1-40	28FEB2012	129.44		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
Placebo	001	1	V1 (WEEK 0)	2009-04-09	10:30	Plasma level Aβ1-40	04AUG2010	73.57		pg/mL
						Plasma level Aβ1-42	04AUG2010	<29.00		pg/mL
					11:15	Albumin (CSF)	02SEP2011	0.39	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	5591.90		pg/mL
						CSF level Aβ1-42	11AUG2010	478.77		pg/mL
			V3 (WEEK 12)	2009-07-07	8:55	CSF level F2-Isoprostane	11AUG2010	57.61		pg/mL
						CSF level Phospho Tau	11AUG2010	194.82	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
						Plasma level Aβ1-40	06AUG2010	85.36		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 001	001	1	V3 (WEEK 12)	2009-07-07	12:05	Albumin (CSF)	02SEP2011	0.29	YES	
						CSF level Aβ1-40	11AUG2010	6935.25	YES	
						CSF level Aβ1-42	11AUG2010	473.25	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	216.27	YES	+
						CSF level Tau protein	11AUG2010	>1200	YES	+
			V4 (WEEK 24)	2009-09-17	11:00	Plasma level Aβ1-40	06AUG2010	104.53	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
			V5 (WEEK 36)	2009-12-10	9:10	Plasma level Aβ1-40	06AUG2010	93.88	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
			V6 (WEEK 52)	2010-04-08	9:00	Plasma level Aβ1-40	06AUG2010	73.83	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.33	YES	+
						CSF level Aβ1-40	11AUG2010	5580.45	YES	
						CSF level Aβ1-42	11AUG2010	465.29	YES	
						CSF level F2-Isoprostane	11AUG2010	55.69	YES	
			V7 (WEEK 56)	2010-05-06	13:15	CSF level Phospho Tau	11AUG2010	181.44	YES	+
						CSF level Tau protein	11AUG2010	>1200	YES	+
						Plasma level Aβ1-40	06AUG2010	113.83	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 001	001	1	V3 (WEEK 12)	2009-07-07	12:05	Albumin (CSF)	02SEP2011	0.29	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	6935.25		pg/mL
						CSF level Aβ1-42	11AUG2010	473.25		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	216.27		pg/mL
						CSF level Tau protein	11AUG2010	>1200		ng/L
			V4 (WEEK 24)	2009-09-17	11:00	Plasma level Aβ1-40	06AUG2010	104.53	116 - 360	pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V5 (WEEK 36)	2009-12-10	9:10	Plasma level Aβ1-40	06AUG2010	93.88		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V6 (WEEK 52)	2010-04-08	9:00	Plasma level Aβ1-40	06AUG2010	73.83		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					11:30	Albumin (CSF)	02SEP2011	0.33		g/L
						CSF level Aβ1-40	11AUG2010	5580.45		pg/mL
			V7 (WEEK 56)	2010-05-06	13:15	CSF level Aβ1-42	11AUG2010	465.29	0.10 - 0.3	pg/mL
						CSF level F2-Isoprostane	11AUG2010	55.69		pg/mL
						CSF level Phospho Tau	11AUG2010	181.44		pg/mL
						CSF level Tau protein	11AUG2010	>1200		ng/L
						Plasma level Aβ1-40	06AUG2010	113.83		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	003	1	V1 (WEEK 0)	2009-05-28	10:00	Albumin (CSF)	02SEP2011	0.23	YES	
						CSF level Aβ1-40	11AUG2010	8482.85	YES	
						CSF level Aβ1-42	11AUG2010	>1000.00	YES	
						CSF level F2-Isoprostane	11AUG2010	51.76	YES	
						CSF level Phospho Tau	11AUG2010	59.70	YES	
						CSF level Tau protein	11AUG2010	543.37	YES	+
			V3 (WEEK 12)	2009-08-25	11:50	Plasma level Aβ1-40	06AUG2010	105.99	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	27.35	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	96.63	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
	005	2	V1 (WEEK 0)	2009-06-04	8:45	Plasma level Aβ1-40	06AUG2010	184.98	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.28	YES	
					11:00	CSF level Aβ1-40	11AUG2010	7737.55	YES	
						CSF level Aβ1-42	11AUG2010	664.97	YES	
						CSF level F2-Isoprostane	11AUG2010	51.00	YES	
						CSF level Phospho Tau	11AUG2010	104.27	YES	+
						CSF level Tau protein	11AUG2010	1111.95	YES	+

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit			
				Date	Time								
Placebo 003	003	1	V1 (WEEK 0)	2009-05-28	10:00	Albumin (CSF)	02SEP2011	0.23	0.10 - 0.3	g/L			
						CSF level Aβ1-40	11AUG2010	8482.85		pg/mL			
						CSF level Aβ1-42	11AUG2010	>1000.00		pg/mL			
						CSF level F2-Isoprostane	11AUG2010	51.76		pg/mL			
						CSF level Phospho Tau	11AUG2010	59.70		< 61	pg/mL		
						CSF level Tau protein	11AUG2010	543.37		116 - 360	ng/L		
				11:25	Plasma level Aβ1-40	06AUG2010	105.99		pg/mL				
					Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL				
			V3 (WEEK 12)	2009-08-25	11:50	Plasma level Aβ1-40	06AUG2010	27.35		pg/mL			
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL			
			V4 (WEEK 24)	2009-11-12	10:15	Plasma level Aβ1-40	06AUG2010	96.63		pg/mL			
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL			
			005	005	2	V1 (WEEK 0)	2009-06-04	8:45	Plasma level Aβ1-40	06AUG2010	184.98	0.10 - 0.3	pg/mL
									Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
								11:00	Albumin (CSF)	02SEP2011	0.28		g/L
									CSF level Aβ1-40	11AUG2010	7737.55		pg/mL
	CSF level Aβ1-42	11AUG2010						664.97	pg/mL				
	CSF level F2-Isoprostane	11AUG2010						51.00	pg/mL				
	CSF level Phospho Tau	11AUG2010						104.27	< 61	pg/mL			
	CSF level Tau protein	11AUG2010						1111.95	170 - 512	ng/L			

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 005	005	2	V3 (WEEK 12)	2009-08-25	8:30	Plasma level Aβ1-40	06AUG2010	195.18	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					11:00	Albumin (CSF)	02SEP2011	0.26	YES	
						CSF level Aβ1-40	11AUG2010	6250.00	YES	
						CSF level Aβ1-42	11AUG2010	663.94	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	91.86	YES	+
			V4 (WEEK 24)	2009-11-18	10:00	CSF level Tau protein	11AUG2010	914.72	YES	+
						Plasma level Aβ1-40	06AUG2010	205.78	YES	
			V5 (WEEK 36)	2010-02-16	9:00	Plasma level Aβ1-42	06AUG2010	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	107.01	YES	
			V6 (WEEK 52)	2010-06-02	9:00	Plasma level Aβ1-42	06AUG2010	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	94.04	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
					10:30	Albumin (CSF)	02SEP2011	0.24	YES	
						CSF level Aβ1-40	11AUG2010	5559.25	YES	
						CSF level Aβ1-42	11AUG2010	580.13	YES	
						CSF level F2-Isoprostane	11AUG2010	52.42	YES	
			V7 (WEEK 56)	2010-07-08	9:15	CSF level Phospho Tau	11AUG2010	89.97	YES	+
						CSF level Tau protein	11AUG2010	919.05	YES	+
						Plasma level Aβ1-40	06AUG2010	180.16	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	005	2	V3 (WEEK 12)	2009-08-25	8:30	Plasma level Aβ1-40	06AUG2010	195.18	0.10 - 0.3	pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					11:00	Albumin (CSF)	02SEP2011	0.26		g/L
						CSF level Aβ1-40	11AUG2010	6250.00		pg/mL
						CSF level Aβ1-42	11AUG2010	663.94		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	91.86		pg/mL
			V4 (WEEK 24)	2009-11-18	10:00	CSF level Tau protein	11AUG2010	914.72	< 61 170 - 512	ng/L
						Plasma level Aβ1-40	06AUG2010	205.78		pg/mL
			V5 (WEEK 36)	2010-02-16	9:00	Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
						Plasma level Aβ1-40	06AUG2010	107.01		pg/mL
			V6 (WEEK 52)	2010-06-02	9:00	Plasma level Aβ1-42	06AUG2010	<29.00	0.10 - 0.3	pg/mL
						Plasma level Aβ1-40	06AUG2010	94.04		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					10:30	Albumin (CSF)	02SEP2011	0.24		g/L
						CSF level Aβ1-40	11AUG2010	5559.25		pg/mL
						CSF level Aβ1-42	11AUG2010	580.13		pg/mL
						CSF level F2-Isoprostane	11AUG2010	52.42		pg/mL
			V7 (WEEK 56)	2010-07-08	9:15	CSF level Phospho Tau	11AUG2010	89.97	< 61 170 - 512	pg/mL
						CSF level Tau protein	11AUG2010	919.05		ng/L
						Plasma level Aβ1-40	06AUG2010	180.16		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	005	2	V7 (WEEK 56)	2010-07-08	9:15	Plasma level Aβ1-42	06AUG2010	<29.00	YES	
	009	1	V1 (WEEK 0)	2009-09-08	9:10	Plasma level Aβ1-40	06AUG2010	74.46		
							02SEP2011	110.94	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.22	YES	
						CSF level Aβ1-40	11AUG2010	9350.25		
							11AUG2011	9966.90	YES	
						CSF level Aβ1-42	11AUG2010	899.26		
							11AUG2011	857.17	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	155.42		+
							11AUG2011	124.28	YES	+
						CSF level Tau protein	11AUG2010	>1200		+
							11AUG2011	978.74	YES	+
			V3 (WEEK 12)	2009-12-10	9:40	Plasma level Aβ1-40	06AUG2010	83.06		
							02SEP2011	116.88	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.19	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	005	2	V7 (WEEK 56)	2010-07-08	9:15	Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
	009	1	V1 (WEEK 0)	2009-09-08	9:10	Plasma level Aβ1-40	06AUG2010	74.46		pg/mL
							02SEP2011	110.94		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.22	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	9350.25		pg/mL
							11AUG2011	9966.90		pg/mL
						CSF level Aβ1-42	11AUG2010	899.26		pg/mL
							11AUG2011	857.17		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	155.42	< 61	pg/mL
							11AUG2011	124.28	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	170 - 512	ng/L
							11AUG2011	978.74	170 - 512	ng/L
			V3 (WEEK 12)	2009-12-10	9:40	Plasma level Aβ1-40	06AUG2010	83.06		pg/mL
							02SEP2011	116.88		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.19	0.10 - 0.3	g/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 009	1	V3 (WEEK 12)	2009-12-10	11:50	CSF level Aβ1-40	11AUG2010	9639.20			
						01SEP2011	9722.40	YES		
						11AUG2010	>1000.00			
						01SEP2011	831.56	YES		
						11AUG2010	<50.00	YES		
						11AUG2010	153.27			+
					CSF level Phospho Tau	01SEP2011	120.03	YES		+
						11AUG2010	>1200			+
					CSF level Tau protein	01SEP2011	954.36	YES		+
						06AUG2010	92.11			
		V4 (WEEK 24)	2010-03-04	12:50	Plasma level Aβ1-40	02SEP2011	144.01	YES		
						06AUG2010	<29.00			
					Plasma level Aβ1-42	02SEP2011	42.76	YES		
		V5 (WEEK 36)	2010-05-11	10:20	Plasma level Aβ1-40	06AUG2010	102.54			
						02SEP2011	157.75	YES		
					Plasma level Aβ1-42	06AUG2010	<29.00			
						02SEP2011	<29.00	YES		
		V6 (WEEK 52)	2010-09-03	10:15	Plasma level Aβ1-40	04AUG2011	107.67	YES		
					Plasma level Aβ1-42	04AUG2011	<29.00	YES		
				13:20	Albumin (CSF)	02SEP2011	0.21	YES		
					CSF level Aβ1-40	11AUG2011	9579.40	YES		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 009	009	1	V3 (WEEK 12)	2009-12-10	11:50	CSF level Aβ1-40	11AUG2010	9639.20		pg/mL
							01SEP2011	9722.40		pg/mL
						CSF level Aβ1-42	11AUG2010	>1000.00		pg/mL
							01SEP2011	831.56		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	153.27	< 61	pg/mL
			V4 (WEEK 24)	2010-03-04	12:50		01SEP2011	120.03	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	170 - 512	ng/L
							01SEP2011	954.36	170 - 512	ng/L
						Plasma level Aβ1-40	06AUG2010	92.11		pg/mL
							02SEP2011	144.01		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V5 (WEEK 36)	2010-05-11	10:20		02SEP2011	42.76		pg/mL
						Plasma level Aβ1-40	06AUG2010	102.54		pg/mL
							02SEP2011	157.75		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V6 (WEEK 52)	2010-09-03	10:15		02SEP2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	107.67		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.21	0.10 - 0.3	g/L
					13:20	CSF level Aβ1-40	11AUG2011	9579.40		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	009	1	V6 (WEEK 52)	2010-09-03	13:20	CSF level Aβ1-42	11AUG2011	950.80	YES	
						CSF level Phospho Tau	11AUG2011	123.21	YES	+
						CSF level Tau protein	11AUG2011	1082.30	YES	+
			V7 (WEEK 56)	2010-10-01	9:15	Plasma level Aβ1-40	04AUG2011	138.28	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	011	1	V1 (WEEK 0)	2009-11-26	10:25	Plasma level Aβ1-40	06AUG2010	103.04		
							02SEP2011	139.60	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	78.67	YES	
							02SEP2011	0.19	YES	
					11:10	Albumin (CSF)	11AUG2010	7182.00		
						CSF level Aβ1-40	01SEP2011	5311.60	YES	
						CSF level Aβ1-42	11AUG2010	793.74		
							01SEP2011	623.41	YES	
						CSF level F2-Isoprostane	11AUG2010	59.99	YES	
					CSF level Phospho Tau	11AUG2010	79.51		+	
						01SEP2011	64.91	YES	+	
					CSF level Tau protein	11AUG2010	735.25		+	
						01SEP2011	415.41	YES	+	
					Plasma level Aβ1-40	06AUG2010	109.51			

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	009	1	V6 (WEEK 52)	2010-09-03	13:20	CSF level Aβ1-42	11AUG2011	950.80		pg/mL
						CSF level Phospho Tau	11AUG2011	123.21	< 61	pg/mL
						CSF level Tau protein	11AUG2011	1082.30	170 - 512	ng/L
			V7 (WEEK 56)	2010-10-01	9:15	Plasma level Aβ1-40	04AUG2011	138.28		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
011	1	V1 (WEEK 0)		2009-11-26	10:25	Plasma level Aβ1-40	06AUG2010	103.04		pg/mL
							02SEP2011	139.60		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
					11:10		02SEP2011	78.67		pg/mL
						Albumin (CSF)	02SEP2011	0.19	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	7182.00		pg/mL
							01SEP2011	5311.60		pg/mL
						CSF level Aβ1-42	11AUG2010	793.74		pg/mL
							01SEP2011	623.41		pg/mL
						CSF level F2-Isoprostane	11AUG2010	59.99		pg/mL
						CSF level Phospho Tau	11AUG2010	79.51	< 61	pg/mL
							01SEP2011	64.91	< 61	pg/mL
						CSF level Tau protein	11AUG2010	735.25	116 - 360	ng/L
							01SEP2011	415.41	116 - 360	ng/L
					9:05	Plasma level Aβ1-40	06AUG2010	109.51		pg/mL

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	011	1	V3 (WEEK 12)	2010-02-18	9:05	Plasma level Aβ1-40	02SEP2011	173.19	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	102.77	YES	
						Albumin (CSF)	02SEP2011	0.18	YES	
					11:10	CSF level Aβ1-40	11AUG2010	6359.80		
							11AUG2011	5869.90	YES	
						CSF level Aβ1-42	11AUG2010	582.64		
							11AUG2011	641.83	YES	
						CSF level F2-Isoprostane	11AUG2010	74.20	YES	
						CSF level Phospho Tau	11AUG2010	85.41		+
							11AUG2011	67.24	YES	+
						CSF level Tau protein	11AUG2010	801.94		+
							11AUG2011	452.56	YES	+
			V4 (WEEK 24)	2010-05-06	13:30	Plasma level Aβ1-40	06AUG2010	128.32		
						Plasma level Aβ1-42	02SEP2011	199.61	YES	
			V5 (WEEK 36)	2010-08-05	12:10		06AUG2010	<29.00		
							02SEP2011	149.35	YES	
			V6 (WEEK 52)	2010-11-26	10:10	Plasma level Aβ1-40	04AUG2011	214.53	YES	
						Plasma level Aβ1-42	04AUG2011	134.50	YES	
						Plasma level Aβ1-40	04AUG2011	167.39	YES	
						Plasma level Aβ1-42	04AUG2011	106.21	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	011	1	V3 (WEEK 12)	2010-02-18	9:05	Plasma level Aβ1-40	02SEP2011	173.19		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	102.77		pg/mL
						Albumin (CSF)	02SEP2011	0.18	0.10 - 0.3	g/L
					11:10	CSF level Aβ1-40	11AUG2010	6359.80		pg/mL
							11AUG2011	5869.90		pg/mL
						CSF level Aβ1-42	11AUG2010	582.64		pg/mL
							11AUG2011	641.83		pg/mL
						CSF level F2-Isoprostane	11AUG2010	74.20		pg/mL
						CSF level Phospho Tau	11AUG2010	85.41	< 61	pg/mL
							11AUG2011	67.24	< 61	pg/mL
						CSF level Tau protein	11AUG2010	801.94	116 - 360	ng/L
							11AUG2011	452.56	116 - 360	ng/L
			V4 (WEEK 24)	2010-05-06	13:30	Plasma level Aβ1-40	06AUG2010	128.32		pg/mL
							02SEP2011	199.61		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	149.35		pg/mL
			V5 (WEEK 36)	2010-08-05	12:10	Plasma level Aβ1-40	04AUG2011	214.53		pg/mL
						Plasma level Aβ1-42	04AUG2011	134.50		pg/mL
			V6 (WEEK 52)	2010-11-26	10:10	Plasma level Aβ1-40	04AUG2011	167.39		pg/mL
						Plasma level Aβ1-42	04AUG2011	106.21		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#		
				Date	Time							
Placebo	011	1	V6 (WEEK 52)	2010-11-26	11:10	Albumin (CSF)	02SEP2011	0.20	YES			
						CSF level Aβ1-40	11AUG2011	5730.50	YES			
						CSF level Aβ1-42	11AUG2011	714.32	YES			
						CSF level Phospho Tau	11AUG2011	63.67	YES	+		
			V7 (WEEK 56)	2010-12-27	12:30	CSF level Tau protein	11AUG2011	462.63	YES	+		
						Plasma level Aβ1-40	04AUG2011	222.20	YES			
						Plasma level Aβ1-42	04AUG2011	135.65	YES			
						013	4	V1 (WEEK 0)	2009-09-16	9:00	Plasma level Aβ1-40	06AUG2010
		02SEP2011	152.76	YES								
	Plasma level Aβ1-42	06AUG2010	<29.00									
		02SEP2011	<29.00	YES								
		12:30	Albumin (CSF)	02SEP2011	0.22						YES	
		CSF level Aβ1-40	11AUG2010	8073.30								
			11AUG2011	8586.60								
		CSF level Aβ1-42	11AUG2010	872.02								
			11AUG2011	928.25								
		CSF level F2-Isoprostane	11AUG2010	<50.00	YES							
		CSF level Phospho Tau	11AUG2010	110.89							+	
			11AUG2011	93.22							+	
		CSF level Tau protein	11AUG2010	>1200		+						

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	011	1	V6 (WEEK 52)	2010-11-26	11:10	Albumin (CSF)	02SEP2011	0.20	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	5730.50		pg/mL
						CSF level Aβ1-42	11AUG2011	714.32		pg/mL
						CSF level Phospho Tau	11AUG2011	63.67		pg/mL
						CSF level Tau protein	11AUG2011	462.63		ng/L
						Plasma level Aβ1-40	04AUG2011	222.20		pg/mL
						Plasma level Aβ1-42	04AUG2011	135.65		pg/mL
	013	4	V1 (WEEK 0)	2009-09-16	9:00	Plasma level Aβ1-40	06AUG2010	99.79	0.10 - 0.3	pg/mL
							02SEP2011	152.76		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
					12:30	Albumin (CSF)	02SEP2011	0.22		g/L
						CSF level Aβ1-40	11AUG2010	8073.30		pg/mL
							11AUG2011	8586.60		pg/mL
						CSF level Aβ1-42	11AUG2010	872.02		pg/mL
							11AUG2011	928.25		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	110.89		pg/mL
							11AUG2011	93.22		pg/mL
						CSF level Tau protein	11AUG2010	>1200		ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	013	4	V1 (WEEK 0)	2009-09-16	12:30	CSF level Tau protein	11AUG2011	806.58		+
			V3 (WEEK 12)	2009-12-09	10:00	Plasma level Aβ1-40	06AUG2010	102.77		
							02SEP2011	150.51	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.22	YES	
						CSF level Aβ1-40	11AUG2010	9534.05		
					13:00		11AUG2011	9833.40	YES	
						CSF level Aβ1-42	11AUG2010	>1000.00		
							11AUG2011	1599.50	YES	
						CSF level F2-Isoprostane	11AUG2010	52.72	YES	
						CSF level Phospho Tau	11AUG2010	106.78		
							11AUG2011	92.42	YES	
						CSF level Tau protein	11AUG2010	1186.15		
							11AUG2011	699.07	YES	
			V4 (WEEK 24)	2010-03-04	10:00	Plasma level Aβ1-40	06AUG2010	103.97		
							02SEP2011	175.97	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
			V5 (WEEK 36)	2010-05-20	10:25	Plasma level Aβ1-40	02SEP2011	<29.00	YES	
							06AUG2010	86.85		
							02SEP2011	78.20	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 013		4	V1 (WEEK 0)	2009-09-16	12:30	CSF level Tau protein	11AUG2011	806.58	170 - 512	ng/L
			V3 (WEEK 12)	2009-12-09	10:00	Plasma level Aβ1-40	06AUG2010	102.77		pg/mL
							02SEP2011	150.51		pg/mL
					13:00	Plasma level Aβ1-42	06AUG2010	<29.00	0.10 - 0.3	pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.22		g/L
						CSF level Aβ1-40	11AUG2010	9534.05		pg/mL
							11AUG2011	9833.40		pg/mL
						CSF level Aβ1-42	11AUG2010	>1000.00		pg/mL
							11AUG2011	1599.50		pg/mL
						CSF level F2-Isoprostane	11AUG2010	52.72	< 61	pg/mL
						CSF level Phospho Tau	11AUG2010	106.78		pg/mL
							11AUG2011	92.42		pg/mL
						CSF level Tau protein	11AUG2010	1186.15	170 - 512	ng/L
							11AUG2011	699.07		ng/L
			V4 (WEEK 24)	2010-03-04	10:00	Plasma level Aβ1-40	06AUG2010	103.97	170 - 512	pg/mL
							02SEP2011	175.97		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V5 (WEEK 36)	2010-05-20	10:25	Plasma level Aβ1-40	02SEP2011	<29.00		pg/mL
							06AUG2010	86.85		pg/mL
							02SEP2011	78.20		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	013	4	V5 (WEEK 36)	2010-05-20	10:25	Plasma level Aβ1-42	06AUG2010	<29.00		
			V6 (WEEK 52)	2010-09-16	11:00	Plasma level Aβ1-40	04AUG2011	154.36	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.22	YES	
						CSF level Aβ1-40	11AUG2011	9137.70	YES	
						CSF level Aβ1-42	11AUG2011	898.66	YES	
						CSF level Phospho Tau	11AUG2011	92.88	YES	+
						CSF level Tau protein	11AUG2011	778.95	YES	+
			V7 (WEEK 56)	2010-10-20	11:45	Plasma level Aβ1-40	04AUG2011	147.60	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	016	4	V1 (WEEK 0)	2010-03-01	10:00	Plasma level Aβ1-40	06AUG2010	84.59		
							02SEP2011	113.11	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	31.47	YES	
						Albumin (CSF)	02SEP2011	0.22	YES	
						CSF level Aβ1-40	11AUG2010	7346.30		
							01SEP2011	7830.30	YES	
						CSF level Aβ1-42	11AUG2010	816.95		
							01SEP2011	782.80	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	013	4	V5 (WEEK 36)	2010-05-20	10:25	Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V6 (WEEK 52)	2010-09-16	11:00		02SEP2011	38.34		pg/mL
						Plasma level Aβ1-40	04AUG2011	154.36		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.22	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	9137.70		pg/mL
						CSF level Aβ1-42	11AUG2011	898.66		pg/mL
						CSF level Phospho Tau	11AUG2011	92.88	< 61	pg/mL
						CSF level Tau protein	11AUG2011	778.95	170 - 512	ng/L
			V7 (WEEK 56)	2010-10-20	11:45	Plasma level Aβ1-40	04AUG2011	147.60		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	016	4	V1 (WEEK 0)	2010-03-01	10:00	Plasma level Aβ1-40	06AUG2010	84.59		pg/mL
							02SEP2011	113.11		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	31.47		pg/mL
						Albumin (CSF)	02SEP2011	0.22	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	7346.30		pg/mL
							01SEP2011	7830.30		pg/mL
						CSF level Aβ1-42	11AUG2010	816.95		pg/mL
							01SEP2011	782.80		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 016	4		V1 (WEEK 0)	2010-03-01	12:00	CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	122.37		+
							01SEP2011	102.67	YES	+
						CSF level Tau protein	11AUG2010	>1200		+
							01SEP2011	634.16	YES	+
			V3 (WEEK 12)	2010-05-19	9:15	Plasma level Aβ1-40	06AUG2010	94.82		
							02SEP2011	140.36	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
			V4 (WEEK 24)	2010-08-09	10:20		02SEP2011	<29.00	YES	
						Plasma level Aβ1-40	04AUG2011	174.11	YES	
			V5 (WEEK 36)	2010-11-08	9:45	Plasma level Aβ1-42	04AUG2011	37.00	YES	
						Plasma level Aβ1-40	04AUG2011	125.23	YES	
			V6 (WEEK 52)	2011-02-28	10:30	Plasma level Aβ1-42	04AUG2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.19	YES	
						CSF level Aβ1-40	11AUG2011	7845.80	YES	
						CSF level Aβ1-42	11AUG2011	769.96	YES	
						CSF level Phospho Tau	11AUG2011	103.60	YES	+
						CSF level Tau protein	11AUG2011	716.30	YES	+
						Plasma level Aβ1-40	04AUG2011	131.08	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V7 (WEEK 56)	2011-04-07	11:00	Plasma level Aβ1-40	04AUG2011	168.92	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 016	016	4	V1 (WEEK 0)	2010-03-01	12:00	CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	122.37	< 61	pg/mL
							01SEP2011	102.67	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
							01SEP2011	634.16	116 - 360	ng/L
			V3 (WEEK 12)	2010-05-19	9:15	Plasma level Aβ1-40	06AUG2010	94.82		pg/mL
							02SEP2011	140.36		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
			V4 (WEEK 24)	2010-08-09	10:20	Plasma level Aβ1-40	04AUG2011	174.11		pg/mL
						Plasma level Aβ1-42	04AUG2011	37.00		pg/mL
			V5 (WEEK 36)	2010-11-08	9:45	Plasma level Aβ1-40	04AUG2011	125.23		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-02-28	10:30	Albumin (CSF)	02SEP2011	0.19	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	7845.80		pg/mL
						CSF level Aβ1-42	11AUG2011	769.96		pg/mL
						CSF level Phospho Tau	11AUG2011	103.60	< 61	pg/mL
						CSF level Tau protein	11AUG2011	716.30	116 - 360	ng/L
						Plasma level Aβ1-40	04AUG2011	131.08		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V7 (WEEK 56)	2011-04-07	11:00	Plasma level Aβ1-40	04AUG2011	168.92		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	016	4	V7 (WEEK 56)	2011-04-07	11:00	Plasma level Aβ1-42	04AUG2011	42.28	YES	
	018	5	V1 (WEEK 0)	2009-11-23	13:00	Plasma level Aβ1-40	06AUG2010	89.66		
						Plasma level Aβ1-42	02SEP2011	130.58	YES	
							06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
					13:15	Albumin (CSF)	02SEP2011	0.29	YES	
						CSF level Aβ1-40	11AUG2010	>10000.00		
							11AUG2011	8048.00	YES	
						CSF level Aβ1-42	11AUG2010	950.14		
							11AUG2011	685.49	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	155.52		+
							11AUG2011	138.50	YES	+
						CSF level Tau protein	11AUG2010	>1200		+
							11AUG2011	1081.50	YES	+
			V3 (WEEK 12)	2010-02-16	12:45	Albumin (CSF)	02SEP2011	0.34	YES	+
						CSF level Aβ1-40	11AUG2010	9026.65		
							01SEP2011	8405.40	YES	
						CSF level Aβ1-42	11AUG2010	832.16		
							01SEP2011	686.35	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	016	4	V7 (WEEK 56)	2011-04-07	11:00	Plasma level Aβ1-42	04AUG2011	42.28		pg/mL
	018	5	V1 (WEEK 0)	2009-11-23	13:00	Plasma level Aβ1-40	06AUG2010	89.66		pg/mL
							02SEP2011	130.58		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.29	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	>10000.00		pg/mL
							11AUG2011	8048.00		pg/mL
						CSF level Aβ1-42	11AUG2010	950.14		pg/mL
							11AUG2011	685.49		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	155.52	< 61	pg/mL
							11AUG2011	138.50	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
							11AUG2011	1081.50	116 - 360	ng/L
						Albumin (CSF)	02SEP2011	0.34	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	9026.65		pg/mL
							01SEP2011	8405.40		pg/mL
						CSF level Aβ1-42	11AUG2010	832.16		pg/mL
							01SEP2011	686.35		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 018	5		V3 (WEEK 12)	2010-02-16	12:45	CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	155.95		+
							01SEP2011	141.34	YES	+
						CSF level Tau protein	11AUG2010	>1200		+
							01SEP2011	1134.30	YES	+
						Plasma level Aβ1-40	06AUG2010	80.98		
			V4 (WEEK 24)	2010-05-11	9:00		02SEP2011	103.46	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	93.28		
							02SEP2011	121.19	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
			V5 (WEEK 36)	2010-07-27	9:00		02SEP2011	<29.00	YES	
						Plasma level Aβ1-40	04AUG2011	119.34	YES	
			V6 (WEEK 52)	2010-11-23	9:20	Plasma level Aβ1-42	04AUG2011	<29.00	YES	
						Plasma level Aβ1-40	04AUG2011	108.14	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
							04AUG2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.31	YES	+
						CSF level Aβ1-40	11AUG2011	8758.60	YES	
				2010-12-02	10:00	CSF level Aβ1-42	11AUG2011	730.41	YES	
						CSF level Phospho Tau	11AUG2011	129.20	YES	+

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 018	5		V3 (WEEK 12)	2010-02-16	12:45	CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	155.95	< 61	pg/mL
							01SEP2011	141.34	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
							01SEP2011	1134.30	116 - 360	ng/L
						Plasma level Aβ1-40	06AUG2010	80.98		pg/mL
			V4 (WEEK 24)	2010-05-11	9:00		02SEP2011	103.46		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Plasma level Aβ1-40	06AUG2010	93.28		pg/mL
							02SEP2011	121.19		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
			V5 (WEEK 36)	2010-07-27	9:00		02SEP2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	119.34		pg/mL
			V6 (WEEK 52)	2010-11-23	9:20	Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	108.14		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	04AUG2011	<29.00		pg/mL
							02SEP2011	0.31	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	8758.60		pg/mL
						CSF level Aβ1-42	11AUG2011	730.41		pg/mL
						CSF level Phospho Tau	11AUG2011	129.20	< 61	pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	018	5	V6 (WEEK 52)	2010-12-02	10:00	CSF level Tau protein	11AUG2011	1077.00	YES	+
			V7 (WEEK 56)	2010-12-14	8:50	Plasma level Aβ1-40	04AUG2011	123.40	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	020	5	V1 (WEEK 0)	2010-02-22	13:00	Albumin (CSF)	02SEP2011	0.22	YES	
						CSF level Aβ1-40	11AUG2010	7183.50	YES	
						CSF level Aβ1-42	11AUG2010	768.07	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	171.15	YES	
						CSF level Tau protein	11AUG2010	>1200	YES	
					13:20	Plasma level Aβ1-40	06AUG2010	79.62	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00	YES	
	024	4	V1 (WEEK 0)	2010-08-16	9:30	Plasma level Aβ1-40	28FEB2012	126.34	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.23		
					12:00		27FEB2012	0.22	YES	
						CSF level Aβ1-40	27FEB2012	11162.00	YES	
						CSF level Aβ1-42	27FEB2012	1084.60	YES	
						CSF level Phospho Tau	27FEB2012	95.70	YES	
						CSF level Tau protein	27FEB2012	849.20	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	018	5	V6 (WEEK 52)	2010-12-02	10:00	CSF level Tau protein	11AUG2011	1077.00	116 - 360	ng/L
			V7 (WEEK 56)	2010-12-14	8:50	Plasma level Aβ1-40	04AUG2011	123.40		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	020	5	V1 (WEEK 0)	2010-02-22	13:00	Albumin (CSF)	02SEP2011	0.22	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	7183.50		pg/mL
						CSF level Aβ1-42	11AUG2010	768.07		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	171.15	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
					13:20	Plasma level Aβ1-40	06AUG2010	79.62		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
	024	4	V1 (WEEK 0)	2010-08-16	9:30	Plasma level Aβ1-40	28FEB2012	126.34		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.23	0.10 - 0.3	g/L
					12:00		27FEB2012	0.22	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	11162.00		pg/mL
						CSF level Aβ1-42	27FEB2012	1084.60		pg/mL
						CSF level Phospho Tau	27FEB2012	95.70	< 61	pg/mL
						CSF level Tau protein	27FEB2012	849.20	170 - 512	ng/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 024	4		V3 (WEEK 12)	2010-11-10	10:20	Plasma level Aβ1-40	28FEB2012	109.36	YES	
			V4 (WEEK 24)	2011-02-02	9:30	Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	100.33	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	141.46	YES	
			V5 (WEEK 36)	2011-04-18	10:00	Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	116.22	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.24		
			V6 (WEEK 52)	2011-08-08	9:30	CSF level Aβ1-40	27FEB2012	8085.40	YES	
						CSF level Aβ1-42	27FEB2012	618.48	YES	
						CSF level Phospho Tau	27FEB2012	98.39	YES	+
						CSF level Tau protein	27FEB2012	885.62	YES	+
						Plasma level Aβ1-40	28FEB2012	122.68	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
028	20		V1 (WEEK 0)	2010-11-26	9:15	Plasma level Aβ1-40	28FEB2012	123.16	YES	
					12:10	Plasma level Aβ1-42	28FEB2012	74.92	YES	
						Albumin (CSF)	27FEB2012	0.29	YES	
						CSF level Aβ1-40	27FEB2012	9378.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 024	024	4	V3 (WEEK 12)	2010-11-10	10:20	Plasma level Aβ1-40	28FEB2012	109.36		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-02-02	9:30	Plasma level Aβ1-40	28FEB2012	100.33		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-04-18	10:00	Plasma level Aβ1-40	28FEB2012	141.46		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-08-08	9:30	Plasma level Aβ1-40	28FEB2012	116.22		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					12:45	Albumin (CSF)	02SEP2011	0.24	0.10 - 0.3	g/L
							27FEB2012	0.28	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	8085.40		pg/mL
						CSF level Aβ1-42	27FEB2012	618.48		pg/mL
						CSF level Phospho Tau	27FEB2012	98.39	< 61	pg/mL
						CSF level Tau protein	27FEB2012	885.62	170 - 512	ng/L
		20	V7 (WEEK 56)	2011-09-12	11:40	Plasma level Aβ1-40	28FEB2012	122.68		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V1 (WEEK 0)	2010-11-26	9:15	Plasma level Aβ1-40	28FEB2012	123.16		pg/mL
						Plasma level Aβ1-42	28FEB2012	74.92		pg/mL
					12:10	Albumin (CSF)	27FEB2012	0.29	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	9378.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	028	20	V1 (WEEK 0)	2010-11-26	12:10	CSF level Aβ1-42	27FEB2012	1613.80	YES	+
						CSF level Phospho Tau	27FEB2012	65.83	YES	
						CSF level Tau protein	27FEB2012	507.68	YES	
			V3 (WEEK 12)	2011-02-22	10:20	Plasma level Aβ1-40	28FEB2012	125.30	YES	
						Plasma level Aβ1-42	28FEB2012	91.01	YES	
			V4 (WEEK 24)	2011-05-24	10:05	Plasma level Aβ1-40	28FEB2012	138.17	YES	
						Plasma level Aβ1-42	28FEB2012	95.48	YES	
			V5 (WEEK 36)	2011-08-25	10:45	Plasma level Aβ1-40	28FEB2012	144.89	YES	
						Plasma level Aβ1-42	28FEB2012	149.75	YES	
			V6 (WEEK 52)	2011-11-24	8:09	Plasma level Aβ1-40	28FEB2012	126.17	YES	
						Plasma level Aβ1-42	28FEB2012	200.04	YES	
			V7 (WEEK 56)	2011-12-20	10:15	Plasma level Aβ1-40	28FEB2012	134.13	YES	
						Plasma level Aβ1-42	28FEB2012	209.10	YES	
	029	8	V1 (WEEK 0)	2010-01-29	10:00	Plasma level Aβ1-40	06AUG2010	85.39		
							02SEP2011	136.78	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.22	YES	
						CSF level Aβ1-40	11AUG2010	6289.80		
					13:24		11AUG2011	7116.40	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	028	20	V1 (WEEK 0)	2010-11-26	12:10	CSF level Aβ1-42	27FEB2012	1613.80	< 61 170 - 512	pg/mL
						CSF level Phospho Tau	27FEB2012	65.83		pg/mL
						CSF level Tau protein	27FEB2012	507.68		ng/L
						Plasma level Aβ1-40	28FEB2012	125.30		pg/mL
			V3 (WEEK 12)	2011-02-22	10:20	Plasma level Aβ1-42	28FEB2012	91.01		pg/mL
						Plasma level Aβ1-40	28FEB2012	138.17		pg/mL
			V4 (WEEK 24)	2011-05-24	10:05	Plasma level Aβ1-42	28FEB2012	95.48		pg/mL
						Plasma level Aβ1-40	28FEB2012	144.89		pg/mL
			V5 (WEEK 36)	2011-08-25	10:45	Plasma level Aβ1-42	28FEB2012	149.75		pg/mL
						Plasma level Aβ1-40	28FEB2012	126.17		pg/mL
			V6 (WEEK 52)	2011-11-24	8:09	Plasma level Aβ1-42	28FEB2012	200.04		pg/mL
						Plasma level Aβ1-40	28FEB2012	134.13		pg/mL
			V7 (WEEK 56)	2011-12-20	10:15	Plasma level Aβ1-40	28FEB2012	209.10		pg/mL
						Plasma level Aβ1-42	28FEB2012	209.10		pg/mL
	029	8	V1 (WEEK 0)	2010-01-29	10:00	Plasma level Aβ1-40	06AUG2010	85.39	0.10 - 0.3	pg/mL
							02SEP2011	136.78		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.22		g/L
						CSF level Aβ1-40	11AUG2010	6289.80		pg/mL
					13:24		11AUG2011	7116.40		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 029	8		V1 (WEEK 0)	2010-01-29	13:24	CSF level Aβ1-42	11AUG2010	820.02		
							11AUG2011	814.04	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	74.50		+
							11AUG2011	57.96	YES	
						CSF level Tau protein	11AUG2010	520.26		+
							11AUG2011	321.13	YES	
						Plasma level Aβ1-40	06AUG2010	89.52		
			V3 (WEEK 12)	2010-04-20	11:50		02SEP2011	133.94	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Plasma level Aβ1-40	04AUG2011	140.29	YES	
			V4 (WEEK 24)	2010-07-05	11:10	Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V5 (WEEK 36)	2010-09-30	11:25	Plasma level Aβ1-40	04AUG2011	157.99	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-02-01	11:45	Plasma level Aβ1-40	04AUG2011	157.59	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V7 (WEEK 56)	2011-02-23	11:05	Plasma level Aβ1-40	04AUG2011	140.78	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
031	8		V1 (WEEK 0)	2010-05-20	10:00	Plasma level Aβ1-40	06AUG2010	66.29		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	029	8	V1 (WEEK 0)	2010-01-29	13:24	CSF level Aβ1-42	11AUG2010	820.02		pg/mL
							11AUG2011	814.04		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	74.50	< 61	pg/mL
							11AUG2011	57.96	< 61	pg/mL
						CSF level Tau protein	11AUG2010	520.26	170 - 512	ng/L
							11AUG2011	321.13	170 - 512	ng/L
			V3 (WEEK 12)	2010-04-20	11:50	Plasma level Aβ1-40	06AUG2010	89.52		pg/mL
							02SEP2011	133.94		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
			V4 (WEEK 24)	2010-07-05	11:10	Plasma level Aβ1-40	04AUG2011	140.29		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V5 (WEEK 36)	2010-09-30	11:25	Plasma level Aβ1-40	04AUG2011	157.99		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-02-01	11:45	Plasma level Aβ1-40	04AUG2011	157.59		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V7 (WEEK 56)	2011-02-23	11:05	Plasma level Aβ1-40	04AUG2011	140.78		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	031	8	V1 (WEEK 0)	2010-05-20	10:00	Plasma level Aβ1-40	06AUG2010	66.29		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	031	8	V1 (WEEK 0)	2010-05-20	10:00	Plasma level Aβ1-40	02SEP2011	101.13	YES	++
						Plasma level Aβ1-42	06AUG2010	<29.00		
					13:30		02SEP2011	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.68	YES	
						CSF level Aβ1-40	11AUG2010	8708.85		
							11AUG2011	8848.00	YES	
						CSF level Aβ1-42	11AUG2010	610.33		
							11AUG2011	659.85	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	224.93		
							11AUG2011	187.47	YES	
						CSF level Tau protein	11AUG2010	>1200		
							11AUG2011	1767.00	YES	
			V4 (WEEK 24)	2010-11-09	11:35	Plasma level Aβ1-40	04AUG2011	108.04	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V5 (WEEK 36)	2011-01-25	12:00	Plasma level Aβ1-40	04AUG2011	134.76	YES	
						Plasma level Aβ1-42	04AUG2011	29.07	YES	
			V6 (WEEK 52)	2011-05-17	11:40	Plasma level Aβ1-40	04AUG2011	110.72	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V7 (WEEK 56)	2011-06-14	10:14	Plasma level Aβ1-40	04AUG2011	113.84	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	031	8	V1 (WEEK 0)	2010-05-20	10:00	Plasma level Aβ1-40	02SEP2011	101.13		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.68	0.10 - 0.3	g/L
					13:30	CSF level Aβ1-40	11AUG2010	8708.85		pg/mL
							11AUG2011	8848.00		pg/mL
						CSF level Aβ1-42	11AUG2010	610.33		pg/mL
							11AUG2011	659.85		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	224.93	< 61	pg/mL
							11AUG2011	187.47	< 61	pg/mL
						CSF level Tau protein	11AUG2010	>1200	116 - 360	ng/L
							11AUG2011	1767.00	116 - 360	ng/L
			V4 (WEEK 24)	2010-11-09	11:35	Plasma level Aβ1-40	04AUG2011	108.04		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V5 (WEEK 36)	2011-01-25	12:00	Plasma level Aβ1-40	04AUG2011	134.76		pg/mL
						Plasma level Aβ1-42	04AUG2011	29.07		pg/mL
			V6 (WEEK 52)	2011-05-17	11:40	Plasma level Aβ1-40	04AUG2011	110.72		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V7 (WEEK 56)	2011-06-14	10:14	Plasma level Aβ1-40	04AUG2011	113.84		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	034	9	V1 (WEEK 0)	2010-03-18	8:50	Plasma level Aβ1-40	06AUG2010	70.60		
							02SEP2011	104.53	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
					12:10	Albumin (CSF)	02SEP2011	0.24	YES	
						CSF level Aβ1-40	11AUG2010	4934.20		
							01SEP2011	4770.20	YES	
						CSF level Aβ1-42	11AUG2010	712.22		
							01SEP2011	661.61	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	69.60		+
							01SEP2011	52.50	YES	
						CSF level Tau protein	11AUG2010	490.35		
							01SEP2011	318.58	YES	
			V3 (WEEK 12)	2010-06-08	9:10	Plasma level Aβ1-40	06AUG2010	81.49		
							02SEP2011	124.46	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
					2010-06-15	11:10	02SEP2011	<29.00	YES	
							02SEP2011	0.25	YES	
							11AUG2010	5041.00		
						CSF level Aβ1-40	01SEP2011	4550.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	034	9	V1 (WEEK 0)	2010-03-18	8:50	Plasma level Aβ1-40	06AUG2010	70.60		pg/mL
							02SEP2011	104.53		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.24	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	4934.20		pg/mL
							01SEP2011	4770.20		pg/mL
						CSF level Aβ1-42	11AUG2010	712.22		pg/mL
							01SEP2011	661.61		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	69.60	< 61	pg/mL
							01SEP2011	52.50	< 61	pg/mL
						CSF level Tau protein	11AUG2010	490.35	170 - 512	ng/L
							01SEP2011	318.58	170 - 512	ng/L
			V3 (WEEK 12)	2010-06-08	9:10	Plasma level Aβ1-40	06AUG2010	81.49		pg/mL
							02SEP2011	124.46		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.25	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	5041.00		pg/mL
							01SEP2011	4550.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 034	9		V3 (WEEK 12)	2010-06-15	11:10	CSF level Aβ1-42	11AUG2010	758.80		+
							01SEP2011	612.77	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	69.61		
							01SEP2011	51.94	YES	
						CSF level Tau protein	11AUG2010	503.17		
							01SEP2011	329.79	YES	
							04AUG2011	90.89	YES	
			V4 (WEEK 24)	2010-09-08	8:40	Plasma level Aβ1-40	04AUG2011	<29.00	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V5 (WEEK 36)	2010-11-30	8:00	Plasma level Aβ1-40	04AUG2011	101.70	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-03-15	8:25	Plasma level Aβ1-40	04AUG2011	93.69	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
							02SEP2011	0.27	YES	
						CSF level Aβ1-40	11AUG2011	4675.30	YES	
						CSF level Aβ1-42	11AUG2011	629.16	YES	
						CSF level Phospho Tau	11AUG2011	49.53	YES	
						CSF level Tau protein	11AUG2011	293.17	YES	
							04AUG2011	107.64	YES	
			V7 (WEEK 56)	2011-04-20	8:25	Plasma level Aβ1-40	04AUG2011	<29.00	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	034	9	V3 (WEEK 12)	2010-06-15	11:10	CSF level Aβ1-42	11AUG2010	758.80		pg/mL
							01SEP2011	612.77		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	69.61	< 61	pg/mL
							01SEP2011	51.94	< 61	pg/mL
						CSF level Tau protein	11AUG2010	503.17	170 - 512	ng/L
							01SEP2011	329.79	170 - 512	ng/L
						V4 (WEEK 24)	04AUG2011	90.89		pg/mL
							04AUG2011	<29.00		pg/mL
			V5 (WEEK 36)	2010-11-30	8:00	Plasma level Aβ1-40	04AUG2011	101.70		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-03-15	8:25	Plasma level Aβ1-40	04AUG2011	93.69		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.27	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	4675.30		pg/mL
						CSF level Aβ1-42	11AUG2011	629.16		pg/mL
						CSF level Phospho Tau	11AUG2011	49.53	< 61	pg/mL
						CSF level Tau protein	11AUG2011	293.17	170 - 512	ng/L
			V7 (WEEK 56)	2011-04-20	8:25	Plasma level Aβ1-40	04AUG2011	107.64		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	041	12	V1 (WEEK 0)	2009-10-09	13:15	Albumin (CSF)	02SEP2011	0.26	YES	
						CSF level Aβ1-40	11AUG2010	7489.35		
							01SEP2011	6920.10	YES	
						CSF level Aβ1-42	11AUG2010	939.03		
							01SEP2011	820.34	YES	
						CSF level F2-Isoprostane	11AUG2010	70.86	YES	
						CSF level Phospho Tau	11AUG2010	83.02		+
							01SEP2011	67.73	YES	+
						CSF level Tau protein	11AUG2010	757.79		+
			V3 (WEEK 12)	2010-01-05	9:40		01SEP2011	473.84	YES	
						Plasma level Aβ1-40	06AUG2010	82.98		
							02SEP2011	93.35	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
						Plasma level Aβ1-40	06AUG2010	105.44		
							02SEP2011	139.12	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
			V4 (WEEK 24)	2010-03-24	9:10	Plasma level Aβ1-40	06AUG2010	176.28		
							02SEP2011	189.59	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	041	12	V1 (WEEK 0)	2009-10-09	13:15	Albumin (CSF)	02SEP2011	0.26	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	7489.35		pg/mL
							01SEP2011	6920.10		pg/mL
						CSF level Aβ1-42	11AUG2010	939.03		pg/mL
							01SEP2011	820.34		pg/mL
						CSF level F2-Isoprostane	11AUG2010	70.86		pg/mL
						CSF level Phospho Tau	11AUG2010	83.02		pg/mL
							01SEP2011	67.73		pg/mL
						CSF level Tau protein	11AUG2010	757.79		ng/L
			V3 (WEEK 12)	2010-01-05	9:40		01SEP2011	473.84	170 - 512	ng/L
						Plasma level Aβ1-40	06AUG2010	82.98		pg/mL
							02SEP2011	93.35		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Plasma level Aβ1-40	06AUG2010	105.44		pg/mL
			V4 (WEEK 24)	2010-03-24	9:10		02SEP2011	139.12		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Plasma level Aβ1-40	06AUG2010	176.28		pg/mL
							02SEP2011	189.59		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	041	12	V4 (WEEK 24)	2010-03-24	9:10	Plasma level Aβ1-42	02SEP2011	<29.00	YES	
			V5 (WEEK 36)	2010-06-16	9:15	Plasma level Aβ1-40	04AUG2011	152.67	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2010-10-06	8:30	Plasma level Aβ1-40	04AUG2011	140.93	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
					11:50	Albumin (CSF)	02SEP2011	0.30	YES	
						CSF level Aβ1-40	11AUG2011	8530.90	YES	
						CSF level Aβ1-42	11AUG2011	867.64	YES	
						CSF level Phospho Tau	11AUG2011	75.63	YES	+
						CSF level Tau protein	11AUG2011	522.42	YES	+
			V7 (WEEK 56)	2010-11-04	8:30	Plasma level Aβ1-40	04AUG2011	178.05	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	044	12	V1 (WEEK 0)	2009-12-02	9:40	Plasma level Aβ1-40	06AUG2010	121.20		
							02SEP2011	139.99	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
			V3 (WEEK 12)	2010-02-24	9:20	Plasma level Aβ1-40	06AUG2010	73.22		
								80.67		
							02SEP2011	131.16		
								135.64	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	041	12	V4 (WEEK 24)	2010-03-24	9:10	Plasma level Aβ1-42	02SEP2011	<29.00		pg/mL
			V5 (WEEK 36)	2010-06-16	9:15	Plasma level Aβ1-40	04AUG2011	152.67		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2010-10-06	8:30	Plasma level Aβ1-40	04AUG2011	140.93		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
					11:50	Albumin (CSF)	02SEP2011	0.30	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	8530.90		pg/mL
						CSF level Aβ1-42	11AUG2011	867.64		pg/mL
						CSF level Phospho Tau	11AUG2011	75.63	< 61	pg/mL
						CSF level Tau protein	11AUG2011	522.42	170 - 512	ng/L
			V7 (WEEK 56)	2010-11-04	8:30	Plasma level Aβ1-40	04AUG2011	178.05		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	044	12	V1 (WEEK 0)	2009-12-02	9:40	Plasma level Aβ1-40	06AUG2010	121.20		pg/mL
							02SEP2011	139.99		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
			V3 (WEEK 12)	2010-02-24	9:20	Plasma level Aβ1-40	06AUG2010	73.22		pg/mL
								80.67		
							02SEP2011	131.16		pg/mL
								135.64		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	044	12	V3 (WEEK 12)	2010-02-24	9:20	Plasma level Aβ1-42	06AUG2010	<29.00		
								<29.00		
							02SEP2011	<29.00		
								<29.00	YES	
			V4 (WEEK 24)	2010-05-26	8:30	Plasma level Aβ1-40	06AUG2010	100.72		
							02SEP2011	181.36	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
			V5 (WEEK 36)	2010-08-18	8:30	Plasma level Aβ1-40	04AUG2011	169.29	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2010-12-01	8:15	Plasma level Aβ1-40	04AUG2011	156.03	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V7 (WEEK 56)	2011-01-05	9:10	Plasma level Aβ1-40	04AUG2011	181.09	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	045	11	V1 (WEEK 0)	2009-12-21	9:15	Plasma level Aβ1-40	06AUG2010	120.32		
							02SEP2011	195.76	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
					11:15	Albumin (CSF)	02SEP2011	0.25	YES	
						CSF level Aβ1-40	11AUG2010	5194.75		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	044	12	V3 (WEEK 12)	2010-02-24	9:20	Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
								<29.00		
							02SEP2011	<29.00		pg/mL
								<29.00		pg/mL
			V4 (WEEK 24)	2010-05-26	8:30	Plasma level Aβ1-40	06AUG2010	100.72		pg/mL
							02SEP2011	181.36		pg/mL
							06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
			V5 (WEEK 36)	2010-08-18	8:30	Plasma level Aβ1-40	04AUG2011	169.29		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2010-12-01	8:15	Plasma level Aβ1-40	04AUG2011	156.03		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V7 (WEEK 56)	2011-01-05	9:10	Plasma level Aβ1-40	04AUG2011	181.09		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	045	11	V1 (WEEK 0)	2009-12-21	9:15	Plasma level Aβ1-40	06AUG2010	120.32		pg/mL
							02SEP2011	195.76		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
					11:15	Albumin (CSF)	02SEP2011	0.25	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2010	5194.75		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	045	11	V1 (WEEK 0)	2009-12-21	11:15	CSF level Aβ1-40	11AUG2011	5038.70	YES	
						CSF level Aβ1-42	11AUG2010	537.76		
							11AUG2011	468.52	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	97.74		+
							11AUG2011	81.76	YES	+
						CSF level Tau protein	11AUG2010	834.89		+
			V4 (WEEK 24)	2010-06-07	9:45		11AUG2011	482.75	YES	+
						Plasma level Aβ1-40	06AUG2010	224.20		
							02SEP2011	283.89	YES	
						Plasma level Aβ1-42	06AUG2010	34.92		
							02SEP2011	49.86	YES	
			V5 (WEEK 36)	2010-09-06	9:15	Plasma level Aβ1-40	04AUG2011	218.82	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2010-12-15	8:30	Plasma level Aβ1-40	04AUG2011	140.93	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V7 (WEEK 56)	2011-01-17	9:05	Plasma level Aβ1-40	04AUG2011	152.53	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	047	11	V1 (WEEK 0)	2010-08-02	8:45	Plasma level Aβ1-40	28FEB2012	92.67	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	045	11	V1 (WEEK 0)	2009-12-21	11:15	CSF level Aβ1-40	11AUG2011	5038.70		pg/mL
						CSF level Aβ1-42	11AUG2010	537.76		pg/mL
							11AUG2011	468.52		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	97.74	< 61	pg/mL
							11AUG2011	81.76	< 61	pg/mL
						CSF level Tau protein	11AUG2010	834.89	116 - 360	ng/L
							11AUG2011	482.75	116 - 360	ng/L
			V4 (WEEK 24)	2010-06-07	9:45	Plasma level Aβ1-40	06AUG2010	224.20		pg/mL
							02SEP2011	283.89		pg/mL
						Plasma level Aβ1-42	06AUG2010	34.92		pg/mL
							02SEP2011	49.86		pg/mL
			V5 (WEEK 36)	2010-09-06	9:15	Plasma level Aβ1-40	04AUG2011	218.82		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2010-12-15	8:30	Plasma level Aβ1-40	04AUG2011	140.93		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
			V7 (WEEK 56)	2011-01-17	9:05	Plasma level Aβ1-40	04AUG2011	152.53		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
	047	11	V1 (WEEK 0)	2010-08-02	8:45	Plasma level Aβ1-40	28FEB2012	92.67		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	047	11	V1 (WEEK 0)	2010-08-02	10:30	Albumin (CSF)	02SEP2011	0.29		
							27FEB2012	0.30	YES	
						CSF level Aβ1-40	27FEB2012	9212.40	YES	
						CSF level Aβ1-42	27FEB2012	1281.70	YES	
						CSF level Phospho Tau	27FEB2012	37.80	YES	
			V3 (WEEK 12)	2010-10-20	11:40	CSF level Tau protein	27FEB2012	284.54	YES	
						Plasma level Aβ1-40	28FEB2012	121.45	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-01-10	9:30	Plasma level Aβ1-40	28FEB2012	143.67	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-04-12	9:15	Plasma level Aβ1-40	28FEB2012	137.87	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-07-27	7:35	Plasma level Aβ1-40	28FEB2012	128.30	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2011-08-29	11:00	Albumin (CSF)	02SEP2011	0.25		
							27FEB2012	0.25	YES	
						CSF level Aβ1-40	27FEB2012	7343.30	YES	
						CSF level Aβ1-42	27FEB2012	1266.70	YES	
						CSF level Phospho Tau	27FEB2012	47.13	YES	
						CSF level Tau protein	27FEB2012	353.62	YES	
					7:45	Plasma level Aβ1-40	28FEB2012	138.22	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	047	11	V1 (WEEK 0)	2010-08-02	10:30	Albumin (CSF)	02SEP2011	0.29	0.10 - 0.3	g/L
							27FEB2012	0.30	0.10 - 0.3	g/L
			V3 (WEEK 12)	2010-10-20	11:40	CSF level Aβ1-40	27FEB2012	9212.40		pg/mL
						CSF level Aβ1-42	27FEB2012	1281.70		pg/mL
						CSF level Phospho Tau	27FEB2012	37.80	< 61	pg/mL
						CSF level Tau protein	27FEB2012	284.54	170 - 512	ng/L
			V4 (WEEK 24)	2011-01-10	9:30	Plasma level Aβ1-40	28FEB2012	121.45		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-04-12	9:15	Plasma level Aβ1-40	28FEB2012	143.67		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-07-27	7:35	Plasma level Aβ1-40	28FEB2012	137.87		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	128.30		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2011-08-29	11:00	Albumin (CSF)	02SEP2011	0.25	0.10 - 0.3	g/L
							27FEB2012	0.25	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	7343.30		pg/mL
						CSF level Aβ1-42	27FEB2012	1266.70		pg/mL
						CSF level Phospho Tau	27FEB2012	47.13	< 61	pg/mL
						CSF level Tau protein	27FEB2012	353.62	170 - 512	ng/L
					7:45	Plasma level Aβ1-40	28FEB2012	138.22		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	047	11	V7 (WEEK 56)	2011-08-29	7:45	Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	049	21	V1 (WEEK 0)	2010-10-27	8:55	Plasma level Aβ1-40	28FEB2012	137.16	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Albumin (CSF)	27FEB2012	0.20	YES	
						CSF level Aβ1-40	27FEB2012	9917.60	YES	
						CSF level Aβ1-42	27FEB2012	1189.80	YES	
						CSF level Phospho Tau	27FEB2012	76.23	YES	+
						CSF level Tau protein	27FEB2012	661.81	YES	+
			V4 (WEEK 24)	2011-04-12	11:00	Plasma level Aβ1-40	28FEB2012	139.49	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-07-05	10:00	Plasma level Aβ1-40	28FEB2012	245.81	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	051	21	V1 (WEEK 0)	2010-10-28	11:30	Plasma level Aβ1-40	28FEB2012	165.36	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	176.85	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	216.82	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-10-25	8:30	Plasma level Aβ1-40	28FEB2012	177.15	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	047	11	V7 (WEEK 56)	2011-08-29	7:45	Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	049	21	V1 (WEEK 0)	2010-10-27	8:55	Plasma level Aβ1-40	28FEB2012	137.16		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	27FEB2012	0.20	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	9917.60		pg/mL
						CSF level Aβ1-42	27FEB2012	1189.80		pg/mL
						CSF level Phospho Tau	27FEB2012	76.23	< 61	pg/mL
						CSF level Tau protein	27FEB2012	661.81	170 - 512	ng/L
			V4 (WEEK 24)	2011-04-12	11:00	Plasma level Aβ1-40	28FEB2012	139.49		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-07-05	10:00	Plasma level Aβ1-40	28FEB2012	245.81		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	051	21	V1 (WEEK 0)	2010-10-28	11:30	Plasma level Aβ1-40	28FEB2012	165.36		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	176.85		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	216.82		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-10-25	8:30	Plasma level Aβ1-40	28FEB2012	177.15		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	051	21	V6 (WEEK 52)	2011-10-25	8:30	Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					10:35	Albumin (CSF)	27FEB2012	0.27	YES	
						CSF level Aβ1-40	27FEB2012	12002.00	YES	
						CSF level Aβ1-42	27FEB2012	1042.60	YES	
						CSF level Phospho Tau	27FEB2012	94.05	YES	+
			V7 (WEEK 56)	2011-11-22	8:30	CSF level Tau protein	27FEB2012	771.28	YES	+
						Plasma level Aβ1-40	28FEB2012	92.88	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	056	5	V1 (WEEK 0)	2010-04-21	9:15	Plasma level Aβ1-40	06AUG2010	113.84		
							02SEP2011	133.09	YES	
						Plasma level Aβ1-42	06AUG2010	<29.00		
							02SEP2011	<29.00	YES	
					12:10	Albumin (CSF)	02SEP2011	0.44	YES	+
						CSF level Aβ1-40	11AUG2010	5518.25		
							11AUG2011	4790.10	YES	
						CSF level Aβ1-42	11AUG2010	460.81		
							11AUG2011	409.38	YES	
						CSF level F2-Isoprostane	11AUG2010	<50.00	YES	
						CSF level Phospho Tau	11AUG2010	93.80		+
							11AUG2011	77.45	YES	+

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	051	21	V6 (WEEK 52)	2011-10-25	8:30	Plasma level Aβ1-42	28FEB2012	<29.00	0.10 - 0.3	pg/mL
					10:35	Albumin (CSF)	27FEB2012	0.27		g/L
						CSF level Aβ1-40	27FEB2012	12002.00		pg/mL
						CSF level Aβ1-42	27FEB2012	1042.60		pg/mL
						CSF level Phospho Tau	27FEB2012	94.05		pg/mL
			V7 (WEEK 56)	2011-11-22	8:30	CSF level Tau protein	27FEB2012	771.28	170 - 512	ng/L
						Plasma level Aβ1-40	28FEB2012	92.88		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	056	5	V1 (WEEK 0)	2010-04-21	9:15	Plasma level Aβ1-40	06AUG2010	113.84	0.10 - 0.3	pg/mL
							02SEP2011	133.09		pg/mL
						Plasma level Aβ1-42	06AUG2010	<29.00		pg/mL
							02SEP2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.44		g/L
						CSF level Aβ1-40	11AUG2010	5518.25		pg/mL
					12:10		11AUG2011	4790.10		pg/mL
						CSF level Aβ1-42	11AUG2010	460.81		pg/mL
							11AUG2011	409.38		pg/mL
						CSF level F2-Isoprostane	11AUG2010	<50.00		pg/mL
						CSF level Phospho Tau	11AUG2010	93.80		pg/mL
							11AUG2011	77.45		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	056	5	V1 (WEEK 0)	2010-04-21	12:10	CSF level Tau protein	11AUG2010	877.67		+
							11AUG2011	528.41	YES	+
			V3 (WEEK 12)	2010-07-13	11:15	Plasma level Aβ1-40	04AUG2011	152.44	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V4 (WEEK 24)	2010-10-05	9:15	Plasma level Aβ1-40	04AUG2011	156.64	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V5 (WEEK 36)	2011-01-04	8:50	Plasma level Aβ1-40	04AUG2011	137.69	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-04-19	8:05	Plasma level Aβ1-40	04AUG2011	116.58	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
					12:20	Albumin (CSF)	02SEP2011	0.43	YES	+
						CSF level Aβ1-40	11AUG2011	5212.70	YES	
						CSF level Aβ1-42	11AUG2011	395.21	YES	
						CSF level Phospho Tau	11AUG2011	82.83	YES	+
						CSF level Tau protein	11AUG2011	585.06	YES	+
			V7 (WEEK 56)	2011-05-18	11:20	Plasma level Aβ1-40	04AUG2011	152.44	YES	
						Plasma level Aβ1-42	04AUG2011	<29.00	YES	
	058	1	V1 (WEEK 0)	2010-12-27	11:15	Plasma level Aβ1-40	28FEB2012	109.78	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					13:35	Albumin (CSF)	02SEP2011	0.20		

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 056	5		V1 (WEEK 0)	2010-04-21	12:10	CSF level Tau protein	11AUG2010	877.67	170 - 512	ng/L
			V3 (WEEK 12)	2010-07-13	11:15		11AUG2011	528.41	170 - 512	ng/L
						Plasma level Aβ1-40	04AUG2011	152.44		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	156.64		pg/mL
			V4 (WEEK 24)	2010-10-05	9:15	Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	137.69		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	116.58		pg/mL
			V5 (WEEK 36)	2011-01-04	8:50	Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	116.58		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	116.58		pg/mL
			V6 (WEEK 52)	2011-04-19	8:05	Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Plasma level Aβ1-40	04AUG2011	116.58		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.43	0.10 - 0.3	g/L
			V7 (WEEK 56)	2011-05-18	11:20	CSF level Aβ1-40	11AUG2011	5212.70		pg/mL
						CSF level Aβ1-42	11AUG2011	395.21		pg/mL
						CSF level Phospho Tau	11AUG2011	82.83	< 61	pg/mL
						CSF level Tau protein	11AUG2011	585.06	170 - 512	ng/L
						Plasma level Aβ1-40	04AUG2011	152.44		pg/mL
						Plasma level Aβ1-42	04AUG2011	<29.00		pg/mL
058	1		V1 (WEEK 0)	2010-12-27	11:15	Plasma level Aβ1-40	28FEB2012	109.78		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					13:35	Albumin (CSF)	02SEP2011	0.20	0.10 - 0.3	g/L

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 058	1		V1 (WEEK 0)	2010-12-27	13:35	Albumin (CSF)	27FEB2012	0.20	YES	
			V3 (WEEK 12)	2011-03-29	11:10	CSF level Aβ1-40	27FEB2012	3841.00	YES	
						CSF level Aβ1-42	27FEB2012	753.15	YES	
						CSF level Phospho Tau	27FEB2012	35.73	YES	
						CSF level Tau protein	27FEB2012	285.26	YES	
						Plasma level Aβ1-40	28FEB2012	99.71	YES	
			V4 (WEEK 24)	2011-06-10	10:15	Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	110.02	YES	
			V5 (WEEK 36)	2011-09-12	10:55	Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	109.30	YES	
			V6 (WEEK 52)	2011-12-06	9:15	Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Plasma level Aβ1-40	28FEB2012	114.26	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Albumin (CSF)	27FEB2012	0.20	YES	
						CSF level Aβ1-40	27FEB2012	4207.50	YES	
			V7 (WEEK 56)	2012-01-10	10:25	CSF level Aβ1-42	27FEB2012	784.33	YES	
						CSF level Phospho Tau	27FEB2012	38.85	YES	
						CSF level Tau protein	27FEB2012	309.87	YES	
						Plasma level Aβ1-40	28FEB2012	110.38	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 058		1	V1 (WEEK 0)	2010-12-27	13:35	Albumin (CSF)	27FEB2012	0.20	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	3841.00		pg/mL
						CSF level Aβ1-42	27FEB2012	753.15		pg/mL
						CSF level Phospho Tau	27FEB2012	35.73		pg/mL
						CSF level Tau protein	27FEB2012	285.26		ng/L
			V3 (WEEK 12)	2011-03-29	11:10	Plasma level Aβ1-40	28FEB2012	99.71		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-06-10	10:15	Plasma level Aβ1-40	28FEB2012	110.02		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-09-12	10:55	Plasma level Aβ1-40	28FEB2012	109.30		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-12-06	9:15	Plasma level Aβ1-40	28FEB2012	114.26		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2011-12-13	10:45	Albumin (CSF)	27FEB2012	0.20	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	4207.50		pg/mL
						CSF level Aβ1-42	27FEB2012	784.33		pg/mL
						CSF level Phospho Tau	27FEB2012	38.85		pg/mL
						CSF level Tau protein	27FEB2012	309.87		ng/L
						Plasma level Aβ1-40	28FEB2012	110.38		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 059	1		V1 (WEEK 0)	2010-12-29	10:05	Plasma level A β 1-40	28FEB2012	90.55	YES	
						Plasma level A β 1-42	28FEB2012	<29.00	YES	
					12:20	Albumin (CSF)	02SEP2011	0.24		
							27FEB2012	0.23	YES	
						CSF level A β 1-40	27FEB2012	4029.90	YES	
						CSF level A β 1-42	27FEB2012	405.89	YES	
						CSF level Phospho Tau	27FEB2012	35.28	YES	
						CSF level Tau protein	27FEB2012	222.57	YES	
			V3 (WEEK 12)	2011-03-31	9:40	Plasma level A β 1-40	28FEB2012	92.16	YES	
						Plasma level A β 1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-06-07	9:00	Plasma level A β 1-40	28FEB2012	99.28	YES	
						Plasma level A β 1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-09-08	10:15	Plasma level A β 1-40	28FEB2012	100.27	YES	
						Plasma level A β 1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-12-06	10:50	Albumin (CSF)	27FEB2012	0.26	YES	
						CSF level A β 1-40	27FEB2012	4077.80	YES	
						CSF level A β 1-42	27FEB2012	548.45	YES	
						CSF level Phospho Tau	27FEB2012	32.84	YES	
						CSF level Tau protein	27FEB2012	214.58	YES	
				2011-12-08	10:00	Plasma level A β 1-40	28FEB2012	83.41	YES	
						Plasma level A β 1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 059	1		V1 (WEEK 0)	2010-12-29	10:05	Plasma level Aβ1-40	28FEB2012	90.55		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					12:20	Albumin (CSF)	02SEP2011	0.24	0.10 - 0.3	g/L
							27FEB2012	0.23	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	4029.90		pg/mL
						CSF level Aβ1-42	27FEB2012	405.89		pg/mL
						CSF level Phospho Tau	27FEB2012	35.28	< 61	pg/mL
						CSF level Tau protein	27FEB2012	222.57	116 - 360	ng/L
			V3 (WEEK 12)	2011-03-31	9:40	Plasma level Aβ1-40	28FEB2012	92.16		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-06-07	9:00	Plasma level Aβ1-40	28FEB2012	99.28		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-09-08	10:15	Plasma level Aβ1-40	28FEB2012	100.27		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-12-06	10:50	Albumin (CSF)	27FEB2012	0.26	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	4077.80		pg/mL
						CSF level Aβ1-42	27FEB2012	548.45		pg/mL
						CSF level Phospho Tau	27FEB2012	32.84	< 61	pg/mL
						CSF level Tau protein	27FEB2012	214.58	116 - 360	ng/L
				2011-12-08	10:00	Plasma level Aβ1-40	28FEB2012	83.41		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	059	1	V7 (WEEK 56)	2012-01-12	11:00	Plasma level Aβ1-40	28FEB2012	104.51	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	065	16	V1 (WEEK 0)	2010-08-30	9:05	Plasma level Aβ1-40	28FEB2012	77.72	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					9:15	Albumin (CSF)	02SEP2011	0.44		+
							27FEB2012	0.47	YES	++
						CSF level Aβ1-40	27FEB2012	4049.50	YES	
						CSF level Aβ1-42	27FEB2012	425.82	YES	
						CSF level Phospho Tau	27FEB2012	95.17	YES	+
						CSF level Tau protein	27FEB2012	1216.60	YES	+
			V3 (WEEK 12)	2010-11-22	10:50	Plasma level Aβ1-40	28FEB2012	91.81	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-01-17	11:50	Plasma level Aβ1-40	28FEB2012	93.40	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	068	16	V1 (WEEK 0)	2010-11-22	9:40	Albumin (CSF)	02SEP2011	0.14		
							27FEB2012	0.15	YES	
						CSF level Aβ1-40	27FEB2012	8182.40	YES	
						CSF level Aβ1-42	27FEB2012	1175.80	YES	
						CSF level Phospho Tau	27FEB2012	55.64	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	059	1	V7 (WEEK 56)	2012-01-12	11:00	Plasma level Aβ1-40	28FEB2012	104.51		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	065	16	V1 (WEEK 0)	2010-08-30	9:05	Plasma level Aβ1-40	28FEB2012	77.72		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					9:15	Albumin (CSF)	02SEP2011	0.44	0.10 - 0.3	g/L
							27FEB2012	0.47	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	4049.50		pg/mL
						CSF level Aβ1-42	27FEB2012	425.82		pg/mL
						CSF level Phospho Tau	27FEB2012	95.17	< 61	pg/mL
						CSF level Tau protein	27FEB2012	1216.60	116 - 360	ng/L
			V3 (WEEK 12)	2010-11-22	10:50	Plasma level Aβ1-40	28FEB2012	91.81		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-01-17	11:50	Plasma level Aβ1-40	28FEB2012	93.40		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	068	16	V1 (WEEK 0)	2010-11-22	9:40	Albumin (CSF)	02SEP2011	0.14	0.10 - 0.3	g/L
							27FEB2012	0.15	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	8182.40		pg/mL
						CSF level Aβ1-42	27FEB2012	1175.80		pg/mL
						CSF level Phospho Tau	27FEB2012	55.64	< 61	pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 068	16		V1 (WEEK 0)	2010-11-22	9:40	CSF level Tau protein	27FEB2012	524.73	YES	+
					10:10	Plasma level Aβ1-40	28FEB2012	140.20	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V3 (WEEK 12)	2011-02-14	9:00	Plasma level Aβ1-40	28FEB2012	130.90	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-05-03	10:30	Plasma level Aβ1-40	28FEB2012	137.55	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-08-10	9:10	Plasma level Aβ1-40	28FEB2012	125.85	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-11-28	10:30	Plasma level Aβ1-40	28FEB2012	132.79	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2012-01-09	11:45	Albumin (CSF)	27FEB2012	0.11	YES	
						CSF level Aβ1-40	27FEB2012	9619.70	YES	
						CSF level Aβ1-42	27FEB2012	1253.20	YES	
						CSF level Phospho Tau	27FEB2012	49.77	YES	
						CSF level Tau protein	27FEB2012	495.68	YES	
						Plasma level Aβ1-40	28FEB2012	118.92	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
069	23		V1 (WEEK 0)	2010-12-07	12:30	Plasma level Aβ1-40	28FEB2012	146.14	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 068	16		V1 (WEEK 0)	2010-11-22	9:40	CSF level Tau protein	27FEB2012	524.73	170 - 512	ng/L
					10:10	Plasma level Aβ1-40	28FEB2012	140.20		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V3 (WEEK 12)	2011-02-14	9:00	Plasma level Aβ1-40	28FEB2012	130.90		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-05-03	10:30	Plasma level Aβ1-40	28FEB2012	137.55		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-08-10	9:10	Plasma level Aβ1-40	28FEB2012	125.85		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-11-28	10:30	Plasma level Aβ1-40	28FEB2012	132.79		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	27FEB2012	0.11	0.10 - 0.3	g/L
			V7 (WEEK 56)	2012-01-09	11:45	CSF level Aβ1-40	27FEB2012	9619.70		pg/mL
						CSF level Aβ1-42	27FEB2012	1253.20		pg/mL
						CSF level Phospho Tau	27FEB2012	49.77	< 61	pg/mL
						CSF level Tau protein	27FEB2012	495.68		ng/L
						Plasma level Aβ1-40	28FEB2012	118.92	170 - 512	pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
069	23		V1 (WEEK 0)	2010-12-07	12:30	Plasma level Aβ1-40	28FEB2012	146.14		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo 069	23	V1 (WEEK 0)	2010-12-07	12:35		Albumin (CSF)	27FEB2012	0.24	YES	
						CSF level Aβ1-40	27FEB2012	2643.70	YES	
						CSF level Aβ1-42	27FEB2012	469.99	YES	
						CSF level Phospho Tau	27FEB2012	<31.00	YES	
						CSF level Tau protein	27FEB2012	103.39	YES	
		V3 (WEEK 12)	2011-03-09	12:20		Plasma level Aβ1-40	28FEB2012	152.36	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
		V4 (WEEK 24)	2011-05-19	9:30		Plasma level Aβ1-40	28FEB2012	169.11	YES	
						Plasma level Aβ1-42	28FEB2012	32.15	YES	
		V5 (WEEK 36)	2011-08-24	11:00		Plasma level Aβ1-40	28FEB2012	149.93	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
		V6 (WEEK 52)	2011-12-14	9:00		Plasma level Aβ1-40	28FEB2012	142.90	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
		V7 (WEEK 56)	2012-01-11	9:00		Albumin (CSF)	27FEB2012	0.35	YES	+
						CSF level Aβ1-40	27FEB2012	2831.30	YES	
						CSF level Aβ1-42	27FEB2012	569.05	YES	
						CSF level Phospho Tau	27FEB2012	<31.00	YES	
						CSF level Tau protein	27FEB2012	91.86	YES	
						Plasma level Aβ1-40	28FEB2012	126.44	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo 069	23	V1 (WEEK 0)	2010-12-07	12:35		Albumin (CSF)	27FEB2012	0.24	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	2643.70		pg/mL
						CSF level Aβ1-42	27FEB2012	469.99	< 61	pg/mL
						CSF level Phospho Tau	27FEB2012	<31.00		pg/mL
						CSF level Tau protein	27FEB2012	103.39	116 - 360	ng/L
						Plasma level Aβ1-40	28FEB2012	152.36		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	169.11		pg/mL
						Plasma level Aβ1-42	28FEB2012	32.15		pg/mL
						Plasma level Aβ1-40	28FEB2012	149.93		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Plasma level Aβ1-40	28FEB2012	142.90		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00	0.10 - 0.3	pg/mL
						Albumin (CSF)	27FEB2012	0.35		g/L
						CSF level Aβ1-40	27FEB2012	2831.30	< 61	pg/mL
						CSF level Aβ1-42	27FEB2012	569.05		pg/mL
						CSF level Phospho Tau	27FEB2012	<31.00	170 - 512	pg/mL
						CSF level Tau protein	27FEB2012	91.86		ng/L
						Plasma level Aβ1-40	28FEB2012	126.44		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	072	18	V1 (WEEK 0)	2010-12-21	12:15	Plasma level Aβ1-40	28FEB2012	127.71	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					14:37	Albumin (CSF)	02SEP2011	0.14		
							27FEB2012	0.15	YES	
			V3 (WEEK 12)	2011-03-15	9:55	CSF level Aβ1-40	27FEB2012	7078.20	YES	
						CSF level Aβ1-42	27FEB2012	901.54	YES	
						CSF level Phospho Tau	27FEB2012	60.28	YES	
						CSF level Tau protein	27FEB2012	446.24	YES	
			V4 (WEEK 24)	2011-06-07	10:01	Plasma level Aβ1-40	28FEB2012	98.47	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-09-08	11:03	Plasma level Aβ1-40	28FEB2012	216.50	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-12-15	9:59	Plasma level Aβ1-40	28FEB2012	150.36	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2012-01-17	9:27	Plasma level Aβ1-40	28FEB2012	127.71	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	079	13	V1 (WEEK 0)	2010-08-06	9:50	Plasma level Aβ1-40	24AUG2011	73.41	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	072	18	V1 (WEEK 0)	2010-12-21	12:15	Plasma level Aβ1-40	28FEB2012	127.71		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					14:37	Albumin (CSF)	02SEP2011	0.14	0.10 - 0.3	g/L
							27FEB2012	0.15	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	7078.20		pg/mL
						CSF level Aβ1-42	27FEB2012	901.54		pg/mL
						CSF level Phospho Tau	27FEB2012	60.28	< 61	pg/mL
						CSF level Tau protein	27FEB2012	446.24	170 - 512	ng/L
			V3 (WEEK 12)	2011-03-15	9:55	Plasma level Aβ1-40	28FEB2012	98.47		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-06-07	10:01	Plasma level Aβ1-40	28FEB2012	216.50		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-09-08	11:03	Plasma level Aβ1-40	28FEB2012	150.36		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-12-15	9:59	Plasma level Aβ1-40	28FEB2012	127.71		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2012-01-17	9:27	Plasma level Aβ1-40	28FEB2012	137.66		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	079	13	V1 (WEEK 0)	2010-08-06	9:50	Plasma level Aβ1-40	24AUG2011	73.41		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Comment
				Date	Time				
Placebo	072	18	V1 (WEEK 0)	2010-12-21	12:15	Plasma level Aβ1-40	28FEB2012	127.71	
						Plasma level Aβ1-42	28FEB2012	<29.00	
					14:37	Albumin (CSF)	02SEP2011	0.14	
							27FEB2012	0.15	
						CSF level Aβ1-40	27FEB2012	7078.20	
						CSF level Aβ1-42	27FEB2012	901.54	
						CSF level Phospho Tau	27FEB2012	60.28	
						CSF level Tau protein	27FEB2012	446.24	
			V3 (WEEK 12)	2011-03-15	9:55	Plasma level Aβ1-40	28FEB2012	98.47	
						Plasma level Aβ1-42	28FEB2012	<29.00	
			V4 (WEEK 24)	2011-06-07	10:01	Plasma level Aβ1-40	28FEB2012	216.50	
						Plasma level Aβ1-42	28FEB2012	<29.00	
			V5 (WEEK 36)	2011-09-08	11:03	Plasma level Aβ1-40	28FEB2012	150.36	
						Plasma level Aβ1-42	28FEB2012	<29.00	
			V6 (WEEK 52)	2011-12-15	9:59	Plasma level Aβ1-40	28FEB2012	127.71	
						Plasma level Aβ1-42	28FEB2012	<29.00	
	079	13	V1 (WEEK 0)	2010-08-06	9:50	Plasma level Aβ1-40	24AUG2011	73.41	HEMOLYTIC
						Plasma level Aβ1-42	24AUG2011	<29.00	HEMOLYTIC

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	079	13	V1 (WEEK 0)	2010-08-12	12:45	Albumin (CSF)	02SEP2011	0.19	YES	
						CSF level Aβ1-40	11AUG2011	6213.40	YES	
						CSF level Aβ1-42	11AUG2011	538.90	YES	
						CSF level Phospho Tau	11AUG2011	78.15	YES	+
						CSF level Tau protein	11AUG2011	540.10	YES	+
			V3 (WEEK 12)	2010-11-09	11:40	Plasma level Aβ1-40	24AUG2011	119.85	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
					14:30	Albumin (CSF)	02SEP2011	0.21	YES	
						CSF level Aβ1-40	11AUG2011	5812.60	YES	
						CSF level Aβ1-42	11AUG2011	695.73	YES	
						CSF level Phospho Tau	11AUG2011	79.19	YES	+
						CSF level Tau protein	11AUG2011	472.37	YES	+
			V4 (WEEK 24)	2011-01-27	13:00	Plasma level Aβ1-40	24AUG2011	141.46	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V5 (WEEK 36)	2011-04-11	11:45	Plasma level Aβ1-40	24AUG2011	115.19	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
			V6 (WEEK 52)	2011-06-21	11:15	Plasma level Aβ1-40	24AUG2011	73.55	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
					15:20	Albumin (CSF)	02SEP2011	0.23	YES	
						CSF level Aβ1-40	11AUG2011	6702.50	YES	
						CSF level Aβ1-42	11AUG2011	748.93	YES	

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	079	13	V1 (WEEK 0)	2010-08-12	12:45	Albumin (CSF)	02SEP2011	0.19	0.10 - 0.3	g/L
						CSF level Aβ1-40	11AUG2011	6213.40		pg/mL
						CSF level Aβ1-42	11AUG2011	538.90		pg/mL
						CSF level Phospho Tau	11AUG2011	78.15		pg/mL
						CSF level Tau protein	11AUG2011	540.10		ng/L
			V3 (WEEK 12)	2010-11-09	11:40	Plasma level Aβ1-40	24AUG2011	119.85	116 - 360	pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.21		g/L
						CSF level Aβ1-40	11AUG2011	5812.60		pg/mL
						CSF level Aβ1-42	11AUG2011	695.73		pg/mL
						CSF level Phospho Tau	11AUG2011	79.19		pg/mL
						CSF level Tau protein	11AUG2011	472.37		ng/L
			V4 (WEEK 24)	2011-01-27	13:00	Plasma level Aβ1-40	24AUG2011	141.46	116 - 360	pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
			V5 (WEEK 36)	2011-04-11	11:45	Plasma level Aβ1-40	24AUG2011	115.19	116 - 360	pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
			V6 (WEEK 52)	2011-06-21	11:15	Plasma level Aβ1-40	24AUG2011	73.55	0.10 - 0.3	pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.23		g/L
						CSF level Aβ1-40	11AUG2011	6702.50		pg/mL
						CSF level Aβ1-42	11AUG2011	748.93		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Comment
				Date	Time				
Placebo	079	13	V1 (WEEK 0)	2010-08-12	12:45	Albumin (CSF)	02SEP2011	0.19	
						CSF level Aβ1-40	11AUG2011	6213.40	
						CSF level Aβ1-42	11AUG2011	538.90	
						CSF level Phospho Tau	11AUG2011	78.15	
						CSF level Tau protein	11AUG2011	540.10	
			V3 (WEEK 12)	2010-11-09	11:40	Plasma level Aβ1-40	24AUG2011	119.85	
						Plasma level Aβ1-42	24AUG2011	<29.00	
					14:30	Albumin (CSF)	02SEP2011	0.21	
						CSF level Aβ1-40	11AUG2011	5812.60	
						CSF level Aβ1-42	11AUG2011	695.73	
			V4 (WEEK 24)	2011-01-27	13:00	CSF level Phospho Tau	11AUG2011	79.19	
						CSF level Tau protein	11AUG2011	472.37	
						Plasma level Aβ1-40	24AUG2011	141.46	
						Plasma level Aβ1-42	24AUG2011	<29.00	
			V5 (WEEK 36)	2011-04-11	11:45	Plasma level Aβ1-40	24AUG2011	115.19	
						Plasma level Aβ1-42	24AUG2011	<29.00	
			V6 (WEEK 52)	2011-06-21	11:15	Plasma level Aβ1-40	24AUG2011	73.55	HEMOLYTIC
						Plasma level Aβ1-42	24AUG2011	<29.00	HEMOLYTIC
					15:20	Albumin (CSF)	02SEP2011	0.23	
						CSF level Aβ1-40	11AUG2011	6702.50	
						CSF level Aβ1-42	11AUG2011	748.93	

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	079	13	V6 (WEEK 52)	2011-06-21	15:20	CSF level Phospho Tau	11AUG2011	72.12	YES	+
						CSF level Tau protein	11AUG2011	483.00	YES	+
			V7 (WEEK 56)	2011-07-19	14:35	Plasma level Aβ1-40	24AUG2011	133.45	YES	
						Plasma level Aβ1-42	24AUG2011	<29.00	YES	
	082	17	V1 (WEEK 0)	2010-10-14	9:00	Plasma level Aβ1-40	28FEB2012	110.34	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					14:00	Albumin (CSF)	02SEP2011	0.47		++
							27FEB2012	0.57	YES	++
						CSF level Aβ1-40	27FEB2012	5951.40	YES	
						CSF level Aβ1-42	27FEB2012	1094.60	YES	
						CSF level Phospho Tau	27FEB2012	31.75	YES	
						CSF level Tau protein	27FEB2012	202.41	YES	
			V4 (WEEK 24)	2011-04-06	9:20	Plasma level Aβ1-40	28FEB2012	97.32	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-06-22	11:15	Plasma level Aβ1-40	28FEB2012	110.83	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-10-12	9:15	Plasma level Aβ1-40	28FEB2012	107.15	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
				2011-10-13	10:15	Albumin (CSF)	27FEB2012	0.04	YES	--
						CSF level Aβ1-40	27FEB2012	2899.10	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	079	13	V6 (WEEK 52)	2011-06-21	15:20	CSF level Phospho Tau	11AUG2011	72.12	< 61	pg/mL
						CSF level Tau protein	11AUG2011	483.00	116 - 360	ng/L
			V7 (WEEK 56)	2011-07-19	14:35	Plasma level Aβ1-40	24AUG2011	133.45		pg/mL
						Plasma level Aβ1-42	24AUG2011	<29.00		pg/mL
	082	17	V1 (WEEK 0)	2010-10-14	9:00	Plasma level Aβ1-40	28FEB2012	110.34		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					14:00	Albumin (CSF)	02SEP2011	0.47	0.10 - 0.3	g/L
							27FEB2012	0.57	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	5951.40		pg/mL
						CSF level Aβ1-42	27FEB2012	1094.60		pg/mL
						CSF level Phospho Tau	27FEB2012	31.75	< 61	pg/mL
						CSF level Tau protein	27FEB2012	202.41	170 - 512	ng/L
			V4 (WEEK 24)	2011-04-06	9:20	Plasma level Aβ1-40	28FEB2012	97.32		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-06-22	11:15	Plasma level Aβ1-40	28FEB2012	110.83		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-10-12	9:15	Plasma level Aβ1-40	28FEB2012	107.15		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
				2011-10-13	10:15	Albumin (CSF)	27FEB2012	0.04	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	2899.10		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	082	17	V6 (WEEK 52)	2011-10-13	10:15	CSF level Aβ1-42	27FEB2012	299.64	YES	
						CSF level Phospho Tau	27FEB2012	<31.00	YES	
						CSF level Tau protein	27FEB2012	212.92	YES	
			V7 (WEEK 56)	2011-11-24	9:20	Plasma level Aβ1-40	28FEB2012	103.30	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	084	17	V1 (WEEK 0)	2010-11-17	9:15	Plasma level Aβ1-40	28FEB2012	123.79	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
						Albumin (CSF)	02SEP2011	0.31		+
					14:00		27FEB2012	0.27	YES	
						CSF level Aβ1-40	27FEB2012	7593.30	YES	
						CSF level Aβ1-42	27FEB2012	654.79	YES	
						CSF level Phospho Tau	27FEB2012	73.26	YES	+
						CSF level Tau protein	27FEB2012	620.89	YES	+
			V4 (WEEK 24)	2011-05-10	10:45	Plasma level Aβ1-40	28FEB2012	113.39	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-08-02	11:15	Plasma level Aβ1-40	28FEB2012	135.05	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-11-23	11:00	Albumin (CSF)	27FEB2012	0.24	YES	
						CSF level Aβ1-40	27FEB2012	3783.10	YES	
						CSF level Aβ1-42	27FEB2012	573.01	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	082	17	V6 (WEEK 52)	2011-10-13	10:15	CSF level Aβ1-42	27FEB2012	299.64		pg/mL
						CSF level Phospho Tau	27FEB2012	<31.00	< 61	pg/mL
						CSF level Tau protein	27FEB2012	212.92	170 - 512	ng/L
			V7 (WEEK 56)	2011-11-24	9:20	Plasma level Aβ1-40	28FEB2012	103.30		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	084	17	V1 (WEEK 0)	2010-11-17	9:15	Plasma level Aβ1-40	28FEB2012	123.79		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
						Albumin (CSF)	02SEP2011	0.31	0.10 - 0.3	g/L
					14:00		27FEB2012	0.27	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	7593.30		pg/mL
						CSF level Aβ1-42	27FEB2012	654.79		pg/mL
						CSF level Phospho Tau	27FEB2012	73.26	< 61	pg/mL
						CSF level Tau protein	27FEB2012	620.89	170 - 512	ng/L
			V4 (WEEK 24)	2011-05-10	10:45	Plasma level Aβ1-40	28FEB2012	113.39		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-08-02	11:15	Plasma level Aβ1-40	28FEB2012	135.05		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-11-23	11:00	Albumin (CSF)	27FEB2012	0.24	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	3783.10		pg/mL
						CSF level Aβ1-42	27FEB2012	573.01		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	084	17	V6 (WEEK 52)	2011-11-23	11:00	CSF level Phospho Tau	27FEB2012	<31.00	YES	
						CSF level Tau protein	27FEB2012	186.93	YES	
			V7 (WEEK 56)	2011-12-15	9:32	Plasma level Aβ1-40	28FEB2012	123.21	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	086	21	V1 (WEEK 0)	2010-10-28	14:05	Plasma level Aβ1-40	28FEB2012	151.17	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					14:50	Albumin (CSF)	27FEB2012	0.13	YES	
						CSF level Aβ1-40	27FEB2012	8946.00	YES	
						CSF level Aβ1-42	27FEB2012	1072.30	YES	
						CSF level Phospho Tau	27FEB2012	73.99	YES	+
						CSF level Tau protein	27FEB2012	556.89	YES	+
			V4 (WEEK 24)	2011-04-12	11:55	Plasma level Aβ1-40	28FEB2012	157.24	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-07-05	11:57	Plasma level Aβ1-40	28FEB2012	258.03	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V6 (WEEK 52)	2011-10-25	11:30	Plasma level Aβ1-40	28FEB2012	146.19	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
					13:40	Albumin (CSF)	27FEB2012	0.15	YES	
						CSF level Aβ1-40	27FEB2012	8192.10	YES	
						CSF level Aβ1-42	27FEB2012	731.10	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	084	17	V6 (WEEK 52)	2011-11-23	11:00	CSF level Phospho Tau	27FEB2012	<31.00	< 61 170 - 512	pg/mL
						CSF level Tau protein	27FEB2012	186.93		ng/L
			V7 (WEEK 56)	2011-12-15	9:32	Plasma level Aβ1-40	28FEB2012	123.21		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	086	21	V1 (WEEK 0)	2010-10-28	14:05	Plasma level Aβ1-40	28FEB2012	151.17	0.10 - 0.3	pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					14:50	Albumin (CSF)	27FEB2012	0.13		g/L
						CSF level Aβ1-40	27FEB2012	8946.00		pg/mL
						CSF level Aβ1-42	27FEB2012	1072.30		pg/mL
						CSF level Phospho Tau	27FEB2012	73.99		pg/mL
						CSF level Tau protein	27FEB2012	556.89		ng/L
			V4 (WEEK 24)	2011-04-12	11:55	Plasma level Aβ1-40	28FEB2012	157.24		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-07-05	11:57	Plasma level Aβ1-40	28FEB2012	258.03		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V6 (WEEK 52)	2011-10-25	11:30	Plasma level Aβ1-40	28FEB2012	146.19		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
					13:40	Albumin (CSF)	27FEB2012	0.15		g/L
						CSF level Aβ1-40	27FEB2012	8192.10		pg/mL
						CSF level Aβ1-42	27FEB2012	731.10		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Value used for analysis	#
				Date	Time					
Placebo	086	21	V6 (WEEK 52)	2011-10-25	13:40	CSF level Phospho Tau	27FEB2012	76.94	YES	+
						CSF level Tau protein	27FEB2012	641.70	YES	+
			V7 (WEEK 56)	2011-11-22	10:10	Plasma level Aβ1-40	28FEB2012	114.94	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
	088	16	V1 (WEEK 0)	2010-12-09	8:45	Albumin (CSF)	02SEP2011	0.23		
							27FEB2012	0.25	YES	
						CSF level Aβ1-40	27FEB2012	9423.80	YES	
						CSF level Aβ1-42	27FEB2012	1138.90	YES	
						CSF level Phospho Tau	27FEB2012	54.44	YES	
						CSF level Tau protein	27FEB2012	332.26	YES	
					9:05	Plasma level Aβ1-40	28FEB2012	105.47	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V3 (WEEK 12)	2011-03-01	10:00	Plasma level Aβ1-40	28FEB2012	114.44	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V4 (WEEK 24)	2011-05-19	9:30	Plasma level Aβ1-40	28FEB2012	129.60	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V5 (WEEK 36)	2011-08-29	9:35	Plasma level Aβ1-40	28FEB2012	131.28	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	
			V7 (WEEK 56)	2012-01-16	9:30	Plasma level Aβ1-40	28FEB2012	108.59	YES	
						Plasma level Aβ1-42	28FEB2012	<29.00	YES	

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Reference range	Unit
				Date	Time					
Placebo	086	21	V6 (WEEK 52)	2011-10-25	13:40	CSF level Phospho Tau	27FEB2012	76.94	< 61	pg/mL
						CSF level Tau protein	27FEB2012	641.70	170 - 512	ng/L
			V7 (WEEK 56)	2011-11-22	10:10	Plasma level Aβ1-40	28FEB2012	114.94		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
	088	16	V1 (WEEK 0)	2010-12-09	8:45	Albumin (CSF)	02SEP2011	0.23	0.10 - 0.3	g/L
							27FEB2012	0.25	0.10 - 0.3	g/L
						CSF level Aβ1-40	27FEB2012	9423.80		pg/mL
						CSF level Aβ1-42	27FEB2012	1138.90		pg/mL
						CSF level Phospho Tau	27FEB2012	54.44	< 61	pg/mL
						CSF level Tau protein	27FEB2012	332.26	116 - 360	ng/L
					9:05	Plasma level Aβ1-40	28FEB2012	105.47		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V3 (WEEK 12)	2011-03-01	10:00	Plasma level Aβ1-40	28FEB2012	114.44		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V4 (WEEK 24)	2011-05-19	9:30	Plasma level Aβ1-40	28FEB2012	129.60		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V5 (WEEK 36)	2011-08-29	9:35	Plasma level Aβ1-40	28FEB2012	131.28		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL
			V7 (WEEK 56)	2012-01-16	9:30	Plasma level Aβ1-40	28FEB2012	108.59		pg/mL
						Plasma level Aβ1-42	28FEB2012	<29.00		pg/mL

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Listing 16.2.6.1: Biomarker concentrations

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Biomarkers

Treat- ment	Ran- dom No.	Site ID	Visit	CSF/Blood sampling		Parameter	Date of entry (MLM)	Result	Comment
				Date	Time				
Placebo	086	21	V6 (WEEK 52)	2011-10-25	13:40	CSF level Phospho Tau	27FEB2012	76.94	
						CSF level Tau protein	27FEB2012	641.70	
			V7 (WEEK 56)	2011-11-22	10:10	Plasma level Aβ1-40	28FEB2012	114.94	
						Plasma level Aβ1-42	28FEB2012	<29.00	
	088	16	V1 (WEEK 0)	2010-12-09	8:45	Albumin (CSF)	02SEP2011	0.23	
							27FEB2012	0.25	
						CSF level Aβ1-40	27FEB2012	9423.80	
						CSF level Aβ1-42	27FEB2012	1138.90	
						CSF level Phospho Tau	27FEB2012	54.44	
						CSF level Tau protein	27FEB2012	332.26	
					9:05	Plasma level Aβ1-40	28FEB2012	105.47	
						Plasma level Aβ1-42	28FEB2012	<29.00	
			V3 (WEEK 12)	2011-03-01	10:00	Plasma level Aβ1-40	28FEB2012	114.44	HEMOLYTIC
						Plasma level Aβ1-42	28FEB2012	<29.00	HEMOLYTIC
			V4 (WEEK 24)	2011-05-19	9:30	Plasma level Aβ1-40	28FEB2012	129.60	
						Plasma level Aβ1-42	28FEB2012	<29.00	
			V5 (WEEK 36)	2011-08-29	9:35	Plasma level Aβ1-40	28FEB2012	131.28	
						Plasma level Aβ1-42	28FEB2012	<29.00	
			V7 (WEEK 56)	2012-01-16	9:30	Plasma level Aβ1-40	28FEB2012	108.59	
						Plasma level Aβ1-42	28FEB2012	<29.00	

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Listing 16.2.6.1: Biomarker concentrations

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BACE Activity

Treat- ment	Random No.	Site ID	Visit	CSF sampling		BACE Activity [ng/mL]	Comment
				Date	Time		
ACI-91	027	20	V1 (WEEK 0)	2010-10-21	12:30	0	at or below detect lim
			V6 (WEEK 52)	2011-10-25	13:45	0.77	
	048	11	V1 (WEEK 0)	2010-11-22	12:30	1.92	
			V6 (WEEK 52)	2011-11-16	13:00	1.75	
	050	21	V1 (WEEK 0)	2010-10-27	14:00	0.66	at or below detect lim
			V6 (WEEK 52)	2011-10-24	11:15	0.71	
	052	21	V1 (WEEK 0)	2010-10-28	11:15	1.2	
			V6 (WEEK 52)	2011-10-24	14:55	0	
	080	13	V1 (WEEK 0)	2010-11-19	14:00	1.04	
			V3 (WEEK 12)	2011-02-09	13:40	1.2	
	083	17	V1 (WEEK 0)	2010-11-10	13:30	0	at or below detect lim
			V6 (WEEK 52)	2011-11-10	9:30	0.38	
	087	16	V1 (WEEK 0)	2010-11-29	9:45	1.92	
			V6 (WEEK 52)	2011-11-28	9:45	1.37	
Placebo	024	4	V1 (WEEK 0)	2010-08-16	12:00	2.35	

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

BACE Activity

Treat- ment	Random No.	Site ID	Visit	CSF sampling		BACE Activity [ng/mL]	Comment
				Date	Time		
Placebo	024	4	V6 (WEEK 52)	2011-08-08	12:45	2.9	
	047	11	V1 (WEEK 0)	2010-08-02	10:30	0.11	at or below detect lim
			V6 (WEEK 52)	2011-07-27	11:00	0	at or below detect lim
	058	1	V1 (WEEK 0)	2010-12-27	13:35	0.27	at or below detect lim
			V6 (WEEK 52)	2011-12-13	10:45	0.16	at or below detect lim
	059	1	V1 (WEEK 0)	2010-12-29	12:20	0.22	at or below detect lim
			V6 (WEEK 52)	2011-12-06	10:50	0	at or below detect lim
	068	16	V1 (WEEK 0)	2010-11-22	9:40	1.31	
			V6 (WEEK 52)	2011-11-28	10:50	0.93	
	069	23	V1 (WEEK 0)	2010-12-07	12:35	0	at or below detect lim
			V6 (WEEK 52)	2011-12-14	10:00	0	at or below detect lim
	082	17	V1 (WEEK 0)	2010-10-14	14:00	0	at or below detect lim
			V6 (WEEK 52)	2011-10-13	10:15	0	at or below detect lim
	084	17	V1 (WEEK 0)	2010-11-17	14:00	2.35	
			V6 (WEEK 52)	2011-11-23	11:00	0	at or below detect lim

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Listing 16.2.6.1: Biomarker concentrations

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BACE Activity

Treat- ment	Random No.	Site ID	Visit	CSF sampling		BACE Activity [ng/mL]	Comment
				Date	Time		
Placebo	086	21	V1 (WEEK 0)	2010-10-28	14:50	0	at or below detect lim
			V6 (WEEK 52)	2011-10-25	13:40	0	at or below detect lim

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Listing 16.2.6.1: Biomarker concentrations

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13FEB2013

Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
ACI-91	002	1	V1 (WEEK 0)	45.0	0.24	5.33
			V3 (WEEK 12)	42.0	0.25	5.95
			V6 (WEEK 52)	46.0	0.26	5.65
	004	1	V1 (WEEK 0)	42.0	0.42	10.00
			V3 (WEEK 12)	42.0	0.42	10.00
			V6 (WEEK 52)	42.0	0.42	10.00
	006	2	V1 (WEEK 0)	49.0	0.33	6.73
			V3 (WEEK 12)	50.0	0.30	6.00
			V6 (WEEK 52)	49.0	0.28	5.71
	010	1	V1 (WEEK 0)	44.0	0.37	8.41
			V3 (WEEK 12)	47.0	0.36	7.66
			V6 (WEEK 52)	47.0	0.36	7.66
	012	1	V1 (WEEK 0)	43.0	0.46	10.70
			V3 (WEEK 12)	43.0	0.46	10.70
			V6 (WEEK 52)	46.0	0.61	13.26
	014	4	V1 (WEEK 0)	43.0	0.21	4.88
			V3 (WEEK 12)	43.0	0.21	4.88
			V6 (WEEK 52)	42.6	0.18	4.23
	015	4	V1 (WEEK 0)	46.0	0.24	5.22
			V3 (WEEK 12)	46.0	0.24	5.22
			V6 (WEEK 52)	47.0	0.25	5.32

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
ACI-91	017	5	V1 (WEEK 0)	47.0	0.23	4.89
			V3 (WEEK 12)	46.2	0.30	6.49
			V6 (WEEK 52)	43.0	0.26	6.05
	019	5	V1 (WEEK 0)	43.0	0.29	6.74
			V3 (WEEK 12)	44.8	0.33	7.37
			V6 (WEEK 52)	44.0	0.31	7.05
	023	4	V1 (WEEK 0)	44.0	0.23	5.23
			V6 (WEEK 52)	46.0	0.21	4.57
	027	20	V1 (WEEK 0)	48.0	0.16	3.33
			V6 (WEEK 52)	44.0	0.16	3.64
	030	8	V1 (WEEK 0)	47.0	0.16	3.40
			V6 (WEEK 52)	49.0	0.18	3.67
	032	8	V1 (WEEK 0)	90.0	0.19	4.22
	033	9	V1 (WEEK 0)	44.0	0.23	5.23
			V6 (WEEK 52)	43.0	0.21	4.88

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
ACI-91	042	12	V1 (WEEK 0)	45.0	0.32	7.11
	043	12	V1 (WEEK 0)	47.0	0.36	7.66
	046	11	V1 (WEEK 0)	38.0	0.45	11.84
			V6 (WEEK 52)	39.2	0.20	5.10
	048	11	V1 (WEEK 0)	50.0	0.27	5.40
				50.0	0.32	6.40
			V6 (WEEK 52)	43.0	0.32	7.44
	050	21	V1 (WEEK 0)	44.0	0.14	3.18
			V6 (WEEK 52)	46.0	0.15	3.26
	052	21	V1 (WEEK 0)	44.8	0.09	2.01
			V6 (WEEK 52)	43.0	0.10	2.33
	055	5	V1 (WEEK 0)	42.1	0.24	5.70
	057	1	V1 (WEEK 0)	44.0	0.14	3.18
				44.0	0.15	3.41

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
ACI-91	066	16	V1 (WEEK 0)	40.9	0.23	5.62
	067	16	V1 (WEEK 0)	43.0	0.29	6.74
	071	18	V1 (WEEK 0)	50.0	0.27	5.40
				50.0	0.28	5.60
	080	13	V1 (WEEK 0)	44.0	0.37	8.41
				44.0	0.41	9.32
			V3 (WEEK 12)	94.0	0.39	8.30
	081	17	V1 (WEEK 0)	47.0	0.31	6.60
				47.0	0.36	7.66
	083	17	V1 (WEEK 0)	46.0	0.06	1.30
				46.0	0.07	1.52
			V6 (WEEK 52)	43.0	0.12	2.79
	087	16	V1 (WEEK 0)	49.0	0.28	5.71
				49.0	0.29	5.92
			V6 (WEEK 52)	49.0	0.30	6.12

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
ACI-91	089	5	V1 (WEEK 0)	44.0	0.27	6.14
				44.0	0.42	9.55
	093	17	V1 (WEEK 0)	48.0	0.35	7.29
				48.0	0.36	7.50
	097	12	V1 (WEEK 0)	48.0	0.40	8.33
				48.0	0.43	8.96
Placebo	001	1	V1 (WEEK 0)	49.3	0.39	7.91
			V3 (WEEK 12)	48.0	0.29	6.04
			V6 (WEEK 52)	48.6	0.33	6.79
	003	1	V1 (WEEK 0)	43.6	0.23	5.28
			V1 (WEEK 0)	43.6	0.23	5.28
			V1 (WEEK 0)	43.6	0.23	5.28
	005	2	V1 (WEEK 0)	39.0	0.28	7.18
			V3 (WEEK 12)	43.1	0.26	6.03
			V6 (WEEK 52)	41.0	0.24	5.85
	009	1	V1 (WEEK 0)	45.9	0.22	4.79
			V3 (WEEK 12)	46.3	0.19	4.10
	009	1	V1 (WEEK 0)	45.9	0.22	4.79
			V3 (WEEK 12)	46.3	0.19	4.10

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
Placebo	009	1	V6 (WEEK 52)	45.0	0.21	4.67
	011	1	V1 (WEEK 0)	48.9	0.19	3.89
			V3 (WEEK 12)	46.0	0.18	3.91
			V6 (WEEK 52)	45.0	0.20	4.44
	013	4	V1 (WEEK 0)	42.0	0.22	5.24
			V3 (WEEK 12)	43.0	0.22	5.12
			V6 (WEEK 52)	44.0	0.22	5.00
	016	4	V1 (WEEK 0)	42.0	0.22	5.24
			V6 (WEEK 52)	45.0	0.19	4.22
	018	5	V1 (WEEK 0)	49.0	0.29	5.92
			V3 (WEEK 12)	46.0	0.34	7.39
			V6 (WEEK 52)	47.0	0.31	6.60
	020	5	V1 (WEEK 0)	47.0	0.22	4.68
	024	4	V1 (WEEK 0)	44.0	0.22	5.00
				44.0	0.23	5.23

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
Placebo	024	4	V6 (WEEK 52)	46.6	0.24	5.15
				46.6	0.28	6.01
	028	20	V1 (WEEK 0)	45.0	0.29	6.44
	029	8	V1 (WEEK 0)	46.0	0.22	4.78
	031	8	V1 (WEEK 0)	48.2	0.68	14.11
	034	9	V1 (WEEK 0)	46.4	0.24	5.17
			V3 (WEEK 12)	44.0	0.25	5.68
			V6 (WEEK 52)	41.9	0.27	6.44
	041	12	V1 (WEEK 0)	44.0	0.26	5.91
			V6 (WEEK 52)	46.0	0.30	6.52
	045	11	V1 (WEEK 0)	47.0	0.25	5.32
	047	11	V1 (WEEK 0)	49.0	0.29	5.92
				49.0	0.30	6.12
			V6 (WEEK 52)	96.0	0.25	5.21

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
Placebo	049	21	V1 (WEEK 0)	46.0	0.20	4.35
	051	21	V6 (WEEK 52)	44.0	0.27	6.14
	056	5	V1 (WEEK 0)	46.1	0.44	9.54
			V6 (WEEK 52)	47.0	0.43	9.15
	058	1	V1 (WEEK 0)	90.0	0.20	4.44
			V6 (WEEK 52)	44.0	0.20	4.55
	059	1	V1 (WEEK 0)	46.0	0.23	5.00
				46.0	0.24	5.22
			V6 (WEEK 52)	47.0	0.26	5.53
	065	16	V1 (WEEK 0)	50.0	0.44	8.80
				50.0	0.47	9.40
	068	16	V1 (WEEK 0)	48.0	0.14	2.92
				48.0	0.15	3.13
			V6 (WEEK 52)	43.0	0.11	2.56

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
Placebo	069	23	V1 (WEEK 0)	43.0	0.24	5.58
			V6 (WEEK 52)	46.0	0.35	7.61
	072	18	V1 (WEEK 0)	50.0	0.14	2.80
				50.0	0.15	3.00
	079	13	V1 (WEEK 0)	50.0	0.19	3.80
			V3 (WEEK 12)	50.0	0.21	4.20
			V6 (WEEK 52)	44.3	0.23	5.19
	082	17	V1 (WEEK 0)	46.0	0.47	10.22
				46.0	0.57	12.39
			V6 (WEEK 52)	50.5	0.04	0.79
	084	17	V1 (WEEK 0)	41.0	0.27	6.59
				41.0	0.31	7.56
			V6 (WEEK 52)	43.0	0.24	5.58
	086	21	V1 (WEEK 0)	44.5	0.13	2.92
			V6 (WEEK 52)	44.0	0.15	3.41

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Listing 16.2.6.1: Biomarker concentrations

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Albumin Index

Treat- ment	Random No.	Site ID	Visit	Albumin		
				Serum [g/L]	CSF [g/L]	Calculated index
Placebo	088	16	V1 (WEEK 0)	43.0	0.23	5.35
				43.0	0.25	5.81

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	002	46	1	SCREENING	55		51	
				V1 (WEEK 0)	45		42	
				V3 (WEEK 12)	46	1	43	1
				V4 (WEEK 24)	39	-6	37	-5
				V5 (WEEK 36)	37	-8	36	-6
				V6 (WEEK 52)	41	-4	40	-2
				V7 (WEEK 56)	37	-8	36	-6
	004	47	1	SCREENING	27		21	
				V1 (WEEK 0)	30		26	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	006	8	2	SCREENING	30		24	
				V1 (WEEK 0)	35		35	
				V3 (WEEK 12)	25	-10	25	-10
				V4 (WEEK 24)	19	-16	19	-16
				V5 (WEEK 36)	25	-10	25	-10
				V6 (WEEK 52)	17	-18	17	-18

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	006	8	2	V7 (WEEK 56)	24	-11	22	-13
	010	10	1	SCREENING	40		35	
				V1 (WEEK 0)	34		26	
				V3 (WEEK 12)	28	-6	25	-1
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	012	67	1	SCREENING	39		33	
				V1 (WEEK 0)	32		28	
				V3 (WEEK 12)	18	-14	14	-14
				V4 (WEEK 24)	24	-8	19	-9
				V5 (WEEK 36)	32	0	23	-5
				V6 (WEEK 52)	29	-3	23	-5
				V7 (WEEK 56)	26	-6	19	-9
	014	22	4	SCREENING	33		32	
				V1 (WEEK 0)	28		21	
				V3 (WEEK 12)	30	2	28	7
				V4 (WEEK 24)	29	1	28	7

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	014	22	4	V5 (WEEK 36)	35	7	33	12
				V6 (WEEK 52)	31	3	27	6
				V7 (WEEK 56)	32	4	29	8
	015	23	4	SCREENING	36		33	
				V1 (WEEK 0)	32		28	
				V3 (WEEK 12)	37	5	35	7
				V4 (WEEK 24)	29	-3	28	0
				V5 (WEEK 36)	43	11	41	13
				V6 (WEEK 52)	35	3	31	3
				V7 (WEEK 56)	31	-1	29	1
	017	17	5	SCREENING	80		70	
				V1 (WEEK 0)	80		75	
				V3 (WEEK 12)	78	-2	61	-14
				V4 (WEEK 24)	77	-3	68	-7
				V5 (WEEK 36)	62	-18	59	-16
				V6 (WEEK 52)	45	-35	39	-36
				V7 (WEEK 56)	68	-12	62	-13
	019	19	5	SCREENING	55		49	
				V1 (WEEK 0)	34		31	

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	019	19	5	V3 (WEEK 12)	43	9	37	6
				V4 (WEEK 24)	45	11	39	8
				V5 (WEEK 36)	46	12	44	13
				V6 (WEEK 52)	44	10	43	12
				V7 (WEEK 56)	46	12	43	12
	023	71	4	SCREENING	18		18	
				V1 (WEEK 0)	23		21	
				V3 (WEEK 12)	12	-11	10	-11
				V4 (WEEK 24)	6	-17	3	-18
				V5 (WEEK 36)	12	-11	10	-11
				V6 (WEEK 52)	0	-23	0	-21
				V7 (WEEK 56)	3	-20	3	-18
	027	87	20	SCREENING	47		39	
				V1 (WEEK 0)	46		41	
				V3 (WEEK 12)	40	-6	38	-3
				V4 (WEEK 24)	44	-2	39	-2
				V5 (WEEK 36)	47	1	44	3
				V6 (WEEK 52)	43	-3	40	-1
				V7 (WEEK 56)	49	3	44	3

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	030	50	8	SCREENING	23		22	
				V1 (WEEK 0)	33		31	
				V3 (WEEK 12)	25	-8	22	-9
				V4 (WEEK 24)	14	-19	11	-20
				V5 (WEEK 36)	14	-19	10	-21
				V6 (WEEK 52)	12	-21	12	-19
				V7 (WEEK 56)	21	-12	19	-12
	032	52	8	SCREENING	62		50	
				V1 (WEEK 0)	52		52	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	033	33	9	SCREENING	30		23	
				V1 (WEEK 0)	54		45	
				V3 (WEEK 12)	43	-11	41	-4
				V4 (WEEK 24)	36	-18	27	-18
				V5 (WEEK 36)	22	-32	20	-25
				V6 (WEEK 52)	34	-20	32	-13

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	033	33	9	V7 (WEEK 56)	30	-24	24	-21
	042	70	12	SCREENING	11		9	
				V1 (WEEK 0)	16		15	
				V3 (WEEK 12)	13	-3	13	-2
				V4 (WEEK 24)	10	-6	9	-6
				V5 (WEEK 36)	9	-7	9	-6
				V6 (WEEK 52)	6	-10	5	-10
				V7 (WEEK 56)	3	-13	3	-12
	043	43	12	SCREENING	10		9	
				V1 (WEEK 0)	15		12	
				V3 (WEEK 12)	8	-7	5	-7
				V4 (WEEK 24)	10	-5	9	-3
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	046	62	11	SCREENING	12		11	
				V1 (WEEK 0)				
				V3 (WEEK 12)	15		13	
				V4 (WEEK 24)	16		15	

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	046	62	11	V5 (WEEK 36)	11		11	
				V6 (WEEK 52)	19		14	
				V7 (WEEK 56)	20		17	
	048	104	11	SCREENING	20		15	
				V1 (WEEK 0)	24		22	
				V3 (WEEK 12)	27	3	23	1
				V4 (WEEK 24)	29	5	25	3
				V5 (WEEK 36)	26	2	25	3
				V6 (WEEK 52)	27	3	24	2
				V7 (WEEK 56)	27	3	23	1
	050	93	21	SCREENING	49		47	
				V1 (WEEK 0)	29		29	
				V3 (WEEK 12)	39	10	35	6
				V4 (WEEK 24)	33	4	31	2
				V5 (WEEK 36)	37	8	34	5
				V6 (WEEK 52)	32	3	29	0
				V7 (WEEK 56)	31	2	30	1
	052	91	21	SCREENING	15		14	
				V1 (WEEK 0)	16		16	

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	052	91	21	V3 (WEEK 12)	12	-4	11	-5
				V4 (WEEK 24)	11	-5	11	-5
				V5 (WEEK 36)	7	-9	7	-9
				V6 (WEEK 52)	11	-5	11	-5
				V7 (WEEK 56)	13	-3	13	-3
	055	76	5	SCREENING	33		26	
				V1 (WEEK 0)	36		26	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)	39	3	35	9
				V7 (WEEK 56)				
	057	68	1	SCREENING	17		14	
				V1 (WEEK 0)	12		10	
				V3 (WEEK 12)	14	2	14	4
				V4 (WEEK 24)	14	2	12	2
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	066	83	16	SCREENING	23		20	
				V1 (WEEK 0)	18		17	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	067	38	16	SCREENING	29		27	
				V1 (WEEK 0)	38		37	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	071	105	18	SCREENING	14		14	
				V1 (WEEK 0)	25		23	
				V3 (WEEK 12)	21	-4	18	-5
				V4 (WEEK 24)	28	3	25	2
				V5 (WEEK 36)	24	-1	21	-2
				V6 (WEEK 52)				

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	071	105	18	V7 (WEEK 56)	18	-7	14	-9
	080	59	13	SCREENING	27		21	
				V1 (WEEK 0)	31		24	
				V3 (WEEK 12)	25	-6	19	-5
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	081	25	17	SCREENING	27		27	
				V1 (WEEK 0)	29		29	
				V3 (WEEK 12)	30	1	29	0
				V4 (WEEK 24)	25	-4	23	-6
				V5 (WEEK 36)	26	-3	23	-6
				V6 (WEEK 52)	18	-11	15	-14
				V7 (WEEK 56)	26	-3	22	-7
	083	27	17	SCREENING	19		18	
				V1 (WEEK 0)	24		22	
				V3 (WEEK 12)	29	5	27	5
				V4 (WEEK 24)	27	3	25	3

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	083	27	17	V5 (WEEK 36)	25	1	21	-1
				V6 (WEEK 52)	27	3	22	0
				V7 (WEEK 56)	27	3	21	-1
	087	39	16	SCREENING	38		36	
				V1 (WEEK 0)	29		26	
				V3 (WEEK 12)	29	0	28	2
				V4 (WEEK 24)	25	-4	24	-2
				V5 (WEEK 36)	30	1	28	2
				V6 (WEEK 52)	23	-6	22	-4
				V7 (WEEK 56)	22	-7	20	-6
		54	16	V3 (WEEK 12)	29		25	
	089	74	5	SCREENING	7		7	
				V1 (WEEK 0)	12		11	
				V3 (WEEK 12)	1	-11	1	-10
				V4 (WEEK 24)				
				V5 (WEEK 36)	3	-9	3	-8
				V6 (WEEK 52)	2	-10	2	-9
				V7 (WEEK 56)	2	-10	1	-10
	093	29	17	SCREENING	22		20	

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	093	29	17	V1 (WEEK 0)	25		23	
				V3 (WEEK 12)	28	3	26	3
				V4 (WEEK 24)	30	5	27	4
				V5 (WEEK 36)	27	2	24	1
				V6 (WEEK 52)	19	-6	12	-11
				V7 (WEEK 56)	20	-5	14	-9
	097	69	12	SCREENING	10		7	
				V1 (WEEK 0)	4		2	
				V3 (WEEK 12)	1	-3	1	-1
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
Placebo	001	48	1	SCREENING	18		13	
				V1 (WEEK 0)	11		11	
				V3 (WEEK 12)	29	18	22	11
				V4 (WEEK 24)	15	4	12	1
				V5 (WEEK 36)	15	4	8	-3
				V6 (WEEK 52)	9	-2	7	-4
				V7 (WEEK 56)	9	-2	7	-4

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	003	45	1	SCREENING	6		4	
				V1 (WEEK 0)	7		5	
				V3 (WEEK 12)	5	-2	2	-3
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	005	5	2	SCREENING	27		27	
				V1 (WEEK 0)	31		31	
				V3 (WEEK 12)	27	-4	27	-4
				V4 (WEEK 24)	33	2	32	1
				V5 (WEEK 36)	32	1	32	1
				V6 (WEEK 52)	35	4	35	4
				V7 (WEEK 56)	25	-6	25	-6
	009	11	1	SCREENING	23		17	
				V1 (WEEK 0)	15		14	
				V3 (WEEK 12)	32	17	19	5
				V4 (WEEK 24)	29	14	25	11
				V5 (WEEK 36)	21	6	14	0
				V6 (WEEK 52)	31	16	24	10

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	009	11	1	V7 (WEEK 56)	31	16	25	11
	011	65	1	SCREENING	23		22	
				V1 (WEEK 0)	32		25	
				V3 (WEEK 12)	36	4	29	4
				V4 (WEEK 24)	33	1	25	0
				V5 (WEEK 36)	30	-2	23	-2
				V6 (WEEK 52)	27	-5	21	-4
				V7 (WEEK 56)	28	-4	25	0
	013	21	4	SCREENING	36		34	
				V1 (WEEK 0)	36		34	
				V3 (WEEK 12)	42	6	39	5
				V4 (WEEK 24)	32	-4	30	-4
				V5 (WEEK 36)	37	1	32	-2
				V6 (WEEK 52)	32	-4	30	-4
				V7 (WEEK 56)	26	-10	25	-9
	016	24	4	SCREENING	41		38	
				V1 (WEEK 0)	40		34	
				V3 (WEEK 12)	48	8	43	9
				V4 (WEEK 24)	48	8	43	9

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	016	24	4	V5 (WEEK 36)	38	-2	35	1
				V6 (WEEK 52)	30	-10	24	-10
				V7 (WEEK 56)	26	-14	19	-15
	018	18	5	SCREENING	23		15	
				V1 (WEEK 0)	25		19	
				V3 (WEEK 12)	15	-10	15	-4
				V4 (WEEK 24)	20	-5	10	-9
				V5 (WEEK 36)	19	-6	15	-4
				V6 (WEEK 52)	12	-13	10	-9
				V7 (WEEK 56)	14	-11	11	-8
	020	20	5	SCREENING	6		4	
				V1 (WEEK 0)	9		5	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	024	72	4	SCREENING	18		16	
				V1 (WEEK 0)	14		14	

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	024	72	4	V3 (WEEK 12)	12	-2	10	-4
				V4 (WEEK 24)	8	-6	7	-7
				V5 (WEEK 36)	17	3	11	-3
				V6 (WEEK 52)	15	1	14	0
				V7 (WEEK 56)	18	4	13	-1
	028	88	20	SCREENING	16		14	
				V1 (WEEK 0)	20		18	
				V3 (WEEK 12)	23	3	15	-3
				V4 (WEEK 24)	18	-2	14	-4
				V5 (WEEK 36)	9	-11	8	-10
				V6 (WEEK 52)	8	-12	6	-12
				V7 (WEEK 56)	9	-11	8	-10
	029	49	8	SCREENING	18		17	
				V1 (WEEK 0)	22		22	
				V3 (WEEK 12)	24	2	22	0
				V4 (WEEK 24)	25	3	25	3
				V5 (WEEK 36)	23	1	20	-2
				V6 (WEEK 52)	24	2	22	0
				V7 (WEEK 56)	22	0	21	-1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	031	51	8	SCREENING	24		23	
				V1 (WEEK 0)	27		26	
				V3 (WEEK 12)	30	3	29	3
				V4 (WEEK 24)	33	6	30	4
				V5 (WEEK 36)	38	11	36	10
				V6 (WEEK 52)	30	3	27	1
				V7 (WEEK 56)	37	10	35	9
	034	34	9	SCREENING	21		18	
				V1 (WEEK 0)	24		20	
				V3 (WEEK 12)	27	3	21	1
				V4 (WEEK 24)	24	0	21	1
				V5 (WEEK 36)	27	3	23	3
				V6 (WEEK 52)	16	-8	16	-4
				V7 (WEEK 56)	21	-3	20	0
	041	41	12	SCREENING	31		30	
				V1 (WEEK 0)	43		41	
				V3 (WEEK 12)	31	-12	31	-10
				V4 (WEEK 24)	40	-3	38	-3
				V5 (WEEK 36)	33	-10	28	-13
				V6 (WEEK 52)	49	6	43	2

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	041	41	12	V7 (WEEK 56)	59	16	53	12
	044	44	12	SCREENING	9		9	
				V1 (WEEK 0)	11		8	
				V3 (WEEK 12)	13	2	13	5
				V4 (WEEK 24)	10	-1	9	1
				V5 (WEEK 36)	9	-2	8	0
				V6 (WEEK 52)	9	-2	8	0
				V7 (WEEK 56)	9	-2	8	0
	045	61	11	SCREENING	32		28	
				V1 (WEEK 0)	36		27	
				V3 (WEEK 12)	26	-10	23	-4
				V4 (WEEK 24)	31	-5	28	1
				V5 (WEEK 36)	22	-14	20	-7
				V6 (WEEK 52)	10	-26	8	-19
				V7 (WEEK 56)	12	-24	11	-16
	047	64	11	SCREENING	32		22	
				V1 (WEEK 0)	32		25	
				V3 (WEEK 12)	38	6	29	4
				V4 (WEEK 24)	33	1	33	8

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	047	64	11	V5 (WEEK 36)	37	5	28	3
				V6 (WEEK 52)	28	-4	25	0
				V7 (WEEK 56)	30	-2	20	-5
	049	90	21	SCREENING	41		40	
				V1 (WEEK 0)	20		17	
				V3 (WEEK 12)	21	1	20	3
				V4 (WEEK 24)	22	2	20	3
				V5 (WEEK 36)	17	-3	15	-2
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	051	92	21	SCREENING	32		30	
				V1 (WEEK 0)	27		26	
				V3 (WEEK 12)	22	-5	22	-4
				V4 (WEEK 24)	22	-5	21	-5
				V5 (WEEK 36)	20	-7	19	-7
				V6 (WEEK 52)	19	-8	19	-7
				V7 (WEEK 56)	16	-11	14	-12
	056	75	5	SCREENING	19		18	
				V1 (WEEK 0)	35		33	

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	056	75	5	V3 (WEEK 12)				
				V4 (WEEK 24)	22	-13	20	-13
				V5 (WEEK 36)	32	-3	30	-3
				V6 (WEEK 52)	22	-13	22	-11
				V7 (WEEK 56)	28	-7	27	-6
	058	110	1	SCREENING	33		30	
				V1 (WEEK 0)	31		25	
				V3 (WEEK 12)	27	-4	22	-3
				V4 (WEEK 24)	32	1	27	2
				V5 (WEEK 36)	23	-8	21	-4
				V6 (WEEK 52)	22	-9	18	-7
				V7 (WEEK 56)	23	-8	19	-6
	059	116	1	SCREENING	33		30	
				V1 (WEEK 0)	33		31	
				V3 (WEEK 12)	34	1	30	-1
				V4 (WEEK 24)	17	-16	12	-19
				V5 (WEEK 36)	33	0	33	2
				V6 (WEEK 52)	27	-6	24	-7
				V7 (WEEK 56)	30	-3	26	-5

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	065	84	16	SCREENING	14		12	
				V1 (WEEK 0)	6		6	
				V3 (WEEK 12)	11	5	11	5
				V4 (WEEK 24)	3	-3	3	-3
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	068	85	16	SCREENING	19		17	
				V1 (WEEK 0)	21		17	
				V3 (WEEK 12)	9	-12	7	-10
				V4 (WEEK 24)	7	-14	6	-11
				V5 (WEEK 36)	12	-9	11	-6
				V6 (WEEK 52)	10	-11	9	-8
				V7 (WEEK 56)	8	-13	4	-13
	069	100	23	SCREENING	26		26	
				V1 (WEEK 0)	19		18	
				V3 (WEEK 12)	27	8	27	9
				V4 (WEEK 24)	28	9	26	8
				V5 (WEEK 36)	33	14	29	11
				V6 (WEEK 52)	19	0	18	0

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	069	100	23	V7 (WEEK 56)	37	18	35	17
	072	106	18	SCREENING	29		23	
				V1 (WEEK 0)	26		19	
				V3 (WEEK 12)	10	-16	9	-10
				V4 (WEEK 24)	6	-20	4	-15
				V5 (WEEK 36)	16	-10	15	-4
				V6 (WEEK 52)	21	-5	18	-1
				V7 (WEEK 56)	12	-14	11	-8
	079	57	13	SCREENING	9		6	
				V1 (WEEK 0)	13		11	
				V3 (WEEK 12)	8	-5	4	-7
				V4 (WEEK 24)	4	-9	4	-7
				V5 (WEEK 36)	1	-12	1	-10
				V6 (WEEK 52)	8	-5	8	-3
				V7 (WEEK 56)	8	-5	4	-7
	082	26	17	SCREENING	31		30	
				V1 (WEEK 0)	39		37	
				V3 (WEEK 12)	30	-9	29	-8
				V4 (WEEK 24)	30	-9	29	-8

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	082	26	17	V5 (WEEK 36)	29	-10	29	-8
				V6 (WEEK 52)	28	-11	26	-11
				V7 (WEEK 56)	29	-10	25	-12
	084	28	17	SCREENING	24		23	
				V1 (WEEK 0)	30		28	
				V3 (WEEK 12)	26	-4	22	-6
				V4 (WEEK 24)	29	-1	26	-2
				V5 (WEEK 36)	27	-3	22	-6
				V6 (WEEK 52)	30	0	25	-3
				V7 (WEEK 56)	31	1	26	-2
	086	112	21	SCREENING	29		28	
				V1 (WEEK 0)	30		30	
				V3 (WEEK 12)	29	-1	28	-2
				V4 (WEEK 24)	26	-4	25	-5
				V5 (WEEK 36)	31	1	30	0
				V6 (WEEK 52)	22	-8	22	-8
				V7 (WEEK 56)	34	4	32	2
	088	40	16	SCREENING	22		19	
				V1 (WEEK 0)	11		10	

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Listing 16.2.6.2: Controlled Oral Word Association Test (COWAT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	088	40	16	V3 (WEEK 12)	19	8	14	4
				V4 (WEEK 24)	8	-3	6	-4
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	002	46	1	SCREENING	16		15	
				V1 (WEEK 0)	19		19	
				V3 (WEEK 12)	15	-4	15	-4
				V4 (WEEK 24)	16	-3	16	-3
				V5 (WEEK 36)	12	-7	11	-8
				V6 (WEEK 52)	12	-7	10	-9
				V7 (WEEK 56)	15	-4	15	-4
	004	47	1	SCREENING	14		14	
				V1 (WEEK 0)	13		12	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	006	8	2	SCREENING	15		15	
				V1 (WEEK 0)	13		13	
				V3 (WEEK 12)	9	-4	9	-4
				V4 (WEEK 24)	7	-6	7	-6
				V5 (WEEK 36)	9	-4	9	-4
				V6 (WEEK 52)	8	-5	8	-5

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	006	8	2	V7 (WEEK 56)	8	-5	8	-5
	010	10	1	SCREENING	11		11	
				V1 (WEEK 0)	16		12	
				V3 (WEEK 12)	11	-5	9	-3
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	012	67	1	SCREENING	6		6	
				V1 (WEEK 0)	12		10	
				V3 (WEEK 12)	6	-6	6	-4
				V4 (WEEK 24)	4	-8	4	-6
				V5 (WEEK 36)	5	-7	4	-6
				V6 (WEEK 52)	5	-7	5	-5
				V7 (WEEK 56)	3	-9	2	-8
	014	22	4	SCREENING	10		10	
				V1 (WEEK 0)	11		10	
				V3 (WEEK 12)	14	3	14	4
				V4 (WEEK 24)	9	-2	9	-1

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	014	22	4	V5 (WEEK 36)	10	-1	10	0
				V6 (WEEK 52)	10	-1	10	0
				V7 (WEEK 56)	12	1	12	2
	015	23	4	SCREENING	10		10	
				V1 (WEEK 0)	11		11	
				V3 (WEEK 12)	10	-1	9	-2
				V4 (WEEK 24)	9	-2	8	-3
				V5 (WEEK 36)	9	-2	9	-2
				V6 (WEEK 52)	8	-3	6	-5
				V7 (WEEK 56)	10	-1	10	-1
	017	17	5	SCREENING	22		21	
				V1 (WEEK 0)	17		16	
				V3 (WEEK 12)	16	-1	16	0
				V4 (WEEK 24)	16	-1	14	-2
				V5 (WEEK 36)	12	-5	12	-4
				V6 (WEEK 52)	10	-7	10	-6
				V7 (WEEK 56)	16	-1	13	-3
	019	19	5	SCREENING	28		23	
				V1 (WEEK 0)	14		14	

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	019	19	5	V3 (WEEK 12)	18	4	18	4
				V4 (WEEK 24)	12	-2	9	-5
				V5 (WEEK 36)	16	2	16	2
				V6 (WEEK 52)	8	-6	8	-6
				V7 (WEEK 56)	22	8	21	7
	023	71	4	SCREENING	7		7	
				V1 (WEEK 0)	9		9	
				V3 (WEEK 12)	6	-3	6	-3
				V4 (WEEK 24)	6	-3	6	-3
				V5 (WEEK 36)	5	-4	5	-4
				V6 (WEEK 52)	4	-5	4	-5
				V7 (WEEK 56)	2	-7	2	-7
	027	87	20	SCREENING	19		19	
				V1 (WEEK 0)	20		20	
				V3 (WEEK 12)	12	-8	11	-9
				V4 (WEEK 24)	13	-7	13	-7
				V5 (WEEK 36)	14	-6	14	-6
				V6 (WEEK 52)	9	-11	9	-11
				V7 (WEEK 56)	20	0	19	-1

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	030	50	8	SCREENING	8		8	
				V1 (WEEK 0)	15		13	
				V3 (WEEK 12)	14	-1	13	0
				V4 (WEEK 24)	8	-7	8	-5
				V5 (WEEK 36)	7	-8	7	-6
				V6 (WEEK 52)	7	-8	6	-7
				V7 (WEEK 56)	12	-3	12	-1
	032	52	8	SCREENING	18		12	
				V1 (WEEK 0)	14		13	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	033	33	9	SCREENING	15		14	
				V1 (WEEK 0)	14		14	
				V3 (WEEK 12)	12	-2	11	-3
				V4 (WEEK 24)	14	0	13	-1
				V5 (WEEK 36)	10	-4	8	-6
				V6 (WEEK 52)	11	-3	11	-3

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	033	33	9	V7 (WEEK 56)	11	-3	11	-3
	042	70	12	SCREENING	12		12	
				V1 (WEEK 0)	12		12	
				V3 (WEEK 12)	8	-4	8	-4
				V4 (WEEK 24)	10	-2	10	-2
				V5 (WEEK 36)	8	-4	8	-4
				V6 (WEEK 52)	5	-7	5	-7
				V7 (WEEK 56)	7	-5	6	-6
	043	43	12	SCREENING	11		11	
				V1 (WEEK 0)	8		8	
				V3 (WEEK 12)	3	-5	2	-6
				V4 (WEEK 24)	7	-1	7	-1
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	046	62	11	SCREENING	9		8	
				V1 (WEEK 0)				
				V3 (WEEK 12)	5		5	
				V4 (WEEK 24)	4		4	

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	046	62	11	V5 (WEEK 36)	5		5	
				V6 (WEEK 52)	5		5	
				V7 (WEEK 56)	5		5	
	048	104	11	SCREENING	9		9	
				V1 (WEEK 0)	7		6	
				V3 (WEEK 12)	5	-2	5	-1
				V4 (WEEK 24)	3	-4	3	-3
				V5 (WEEK 36)	8	1	8	2
				V6 (WEEK 52)	4	-3	4	-2
				V7 (WEEK 56)	3	-4	2	-4
	050	93	21	SCREENING	10		10	
				V1 (WEEK 0)	13		13	
				V3 (WEEK 12)	7	-6	7	-6
				V4 (WEEK 24)	9	-4	9	-4
				V5 (WEEK 36)	10	-3	10	-3
				V6 (WEEK 52)	9	-4	9	-4
				V7 (WEEK 56)	12	-1	12	-1
	052	91	21	SCREENING	7		7	
				V1 (WEEK 0)	7		7	

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	052	91	21	V3 (WEEK 12)	6	-1	6	-1
				V4 (WEEK 24)	6	-1	6	-1
				V5 (WEEK 36)	3	-4	3	-4
				V6 (WEEK 52)	5	-2	4	-3
				V7 (WEEK 56)	3	-4	3	-4
	055	76	5	SCREENING	12		12	
				V1 (WEEK 0)	16		16	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)	16	0	15	-1
				V7 (WEEK 56)				
	057	68	1	SCREENING	7		7	
				V1 (WEEK 0)	6		6	
				V3 (WEEK 12)	6	0	5	-1
				V4 (WEEK 24)	3	-3	3	-3
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	066	83	16	SCREENING	10		10	
				V1 (WEEK 0)	7		7	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	067	38	16	SCREENING	25		24	
				V1 (WEEK 0)	20		19	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	071	105	18	SCREENING	5		5	
				V1 (WEEK 0)	5		5	
				V3 (WEEK 12)	7	2	6	1
				V4 (WEEK 24)	3	-2	3	-2
				V5 (WEEK 36)	4	-1	4	-1
				V6 (WEEK 52)				

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	071	105	18	V7 (WEEK 56)	3	-2	2	-3
	080	59	13	SCREENING	17		16	
				V1 (WEEK 0)	17		15	
				V3 (WEEK 12)	12	-5	10	-5
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	081	25	17	SCREENING	15		15	
				V1 (WEEK 0)	13		13	
				V3 (WEEK 12)	13	0	13	0
				V4 (WEEK 24)	8	-5	8	-5
				V5 (WEEK 36)	11	-2	11	-2
				V6 (WEEK 52)	8	-5	7	-6
				V7 (WEEK 56)	10	-3	8	-5
	083	27	17	SCREENING	10		10	
				V1 (WEEK 0)	10		10	
				V3 (WEEK 12)	12	2	11	1
				V4 (WEEK 24)	8	-2	8	-2

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	083	27	17	V5 (WEEK 36)	9	-1	9	-1
				V6 (WEEK 52)	8	-2	7	-3
				V7 (WEEK 56)	11	1	10	0
	087	39	16	SCREENING	15		13	
				V1 (WEEK 0)	12		12	
				V3 (WEEK 12)	9	-3	9	-3
				V4 (WEEK 24)	7	-5	6	-6
				V5 (WEEK 36)	11	-1	7	-5
				V6 (WEEK 52)	8	-4	5	-7
				V7 (WEEK 56)	5	-7	2	-10
		54	16	V3 (WEEK 12)	12		11	
	089	74	5	SCREENING	6		5	
				V1 (WEEK 0)	6		6	
				V3 (WEEK 12)	0	-6	0	-6
				V4 (WEEK 24)				
				V5 (WEEK 36)	3	-3	3	-3
				V6 (WEEK 52)	3	-3	3	-3
				V7 (WEEK 56)	1	-5	1	-5
	093	29	17	SCREENING	10		10	

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
ACI-91	093	29	17	V1 (WEEK 0)	14		13	
				V3 (WEEK 12)	13	-1	12	-1
				V4 (WEEK 24)	14	0	13	0
				V5 (WEEK 36)	10	-4	8	-5
				V6 (WEEK 52)	7	-7	5	-8
				V7 (WEEK 56)	10	-4	6	-7
	097	69	12	SCREENING	3		3	
				V1 (WEEK 0)	4		4	
				V3 (WEEK 12)	2	-2	2	-2
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
Placebo	001	48	1	SCREENING	6		6	
				V1 (WEEK 0)	10		7	
				V3 (WEEK 12)	12	2	12	5
				V4 (WEEK 24)	7	-3	6	-1
				V5 (WEEK 36)	5	-5	5	-2
				V6 (WEEK 52)	9	-1	8	1
				V7 (WEEK 56)	5	-5	4	-3

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	003	45	1	SCREENING	4		3	
				V1 (WEEK 0)	5		5	
				V3 (WEEK 12)	5	0	5	0
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	005	5	2	SCREENING	9		9	
				V1 (WEEK 0)	11		11	
				V3 (WEEK 12)	10	-1	10	-1
				V4 (WEEK 24)	11	0	11	0
				V5 (WEEK 36)	10	-1	10	-1
				V6 (WEEK 52)	14	3	14	3
				V7 (WEEK 56)	15	4	15	4
	009	11	1	SCREENING	12		8	
				V1 (WEEK 0)	1		1	
				V3 (WEEK 12)	11	10	7	6
				V4 (WEEK 24)	12	11	11	10
				V5 (WEEK 36)	9	8	7	6
				V6 (WEEK 52)	5	4	3	2

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	009	11	1	V7 (WEEK 56)	11	10	7	6
	011	65	1	SCREENING	13		11	
				V1 (WEEK 0)	14		11	
				V3 (WEEK 12)	10	-4	10	-1
				V4 (WEEK 24)	12	-2	11	0
				V5 (WEEK 36)	15	1	12	1
				V6 (WEEK 52)	8	-6	8	-3
				V7 (WEEK 56)	8	-6	8	-3
	013	21	4	SCREENING	17		16	
				V1 (WEEK 0)	16		16	
				V3 (WEEK 12)	12	-4	12	-4
				V4 (WEEK 24)	17	1	16	0
				V5 (WEEK 36)	11	-5	11	-5
				V6 (WEEK 52)	9	-7	9	-7
				V7 (WEEK 56)	11	-5	11	-5
	016	24	4	SCREENING	21		21	
				V1 (WEEK 0)	21		21	
				V3 (WEEK 12)	19	-2	17	-4
				V4 (WEEK 24)	20	-1	20	-1

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	016	24	4	V5 (WEEK 36)	18	-3	18	-3
				V6 (WEEK 52)	11	-10	11	-10
				V7 (WEEK 56)	12	-9	12	-9
	018	18	5	SCREENING	3		2	
				V1 (WEEK 0)	3		2	
				V3 (WEEK 12)	7	4	3	1
				V4 (WEEK 24)	2	-1	2	0
				V5 (WEEK 36)	3	0	2	0
				V6 (WEEK 52)	3	0	3	1
				V7 (WEEK 56)	2	-1	2	0
	020	20	5	SCREENING	7		5	
				V1 (WEEK 0)	5		5	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	024	72	4	SCREENING	8		7	
				V1 (WEEK 0)	14		13	

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	024	72	4	V3 (WEEK 12)	8	-6	8	-5
				V4 (WEEK 24)	12	-2	12	-1
				V5 (WEEK 36)	13	-1	12	-1
				V6 (WEEK 52)	8	-6	8	-5
				V7 (WEEK 56)	9	-5	9	-4
	028	88	20	SCREENING	2		2	
				V1 (WEEK 0)	3		3	
				V3 (WEEK 12)	1	-2	1	-2
				V4 (WEEK 24)	1	-2	1	-2
				V5 (WEEK 36)	0	-3	0	-3
				V6 (WEEK 52)	2	-1	2	-1
				V7 (WEEK 56)	1	-2	1	-2
	029	49	8	SCREENING	12		12	
				V1 (WEEK 0)	13		13	
				V3 (WEEK 12)	14	1	14	1
				V4 (WEEK 24)	13	0	13	0
				V5 (WEEK 36)	11	-2	11	-2
				V6 (WEEK 52)	12	-1	12	-1
				V7 (WEEK 56)	13	0	13	0

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	031	51	8	SCREENING	12		10	
				V1 (WEEK 0)	10		10	
				V3 (WEEK 12)	14	4	13	3
				V4 (WEEK 24)	8	-2	7	-3
				V5 (WEEK 36)	11	1	11	1
				V6 (WEEK 52)	8	-2	8	-2
				V7 (WEEK 56)	11	1	11	1
	034	34	9	SCREENING	10		8	
				V1 (WEEK 0)	7		7	
				V3 (WEEK 12)	17	10	16	9
				V4 (WEEK 24)	8	1	7	0
				V5 (WEEK 36)	12	5	10	3
				V6 (WEEK 52)	7	0	6	-1
				V7 (WEEK 56)	10	3	9	2
	041	41	12	SCREENING	15		15	
				V1 (WEEK 0)	9		9	
				V3 (WEEK 12)	12	3	10	1
				V4 (WEEK 24)	12	3	10	1
				V5 (WEEK 36)	11	2	11	2
				V6 (WEEK 52)	13	4	11	2

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	041	41	12	V7 (WEEK 56)	10	1	8	-1
	044	44	12	SCREENING	8		8	
				V1 (WEEK 0)	10		10	
				V3 (WEEK 12)	12	2	12	2
				V4 (WEEK 24)	9	-1	9	-1
				V5 (WEEK 36)	5	-5	5	-5
				V6 (WEEK 52)	3	-7	3	-7
				V7 (WEEK 56)	9	-1	9	-1
	045	61	11	SCREENING	9		9	
				V1 (WEEK 0)	11		11	
				V3 (WEEK 12)	12	1	12	1
				V4 (WEEK 24)	12	1	12	1
				V5 (WEEK 36)	10	-1	10	-1
				V6 (WEEK 52)	5	-6	5	-6
				V7 (WEEK 56)	3	-8	3	-8
	047	64	11	SCREENING	14		11	
				V1 (WEEK 0)	16		14	
				V3 (WEEK 12)	14	-2	12	-2
				V4 (WEEK 24)	16	0	16	2

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	047	64	11	V5 (WEEK 36)	15	-1	11	-3
				V6 (WEEK 52)	14	-2	14	0
				V7 (WEEK 56)	10	-6	9	-5
	049	90	21	SCREENING	9		9	
				V1 (WEEK 0)	9		9	
				V3 (WEEK 12)	12	3	10	1
				V4 (WEEK 24)	9	0	8	-1
				V5 (WEEK 36)	9	0	9	0
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	051	92	21	SCREENING	7		7	
				V1 (WEEK 0)	10		10	
				V3 (WEEK 12)	11	1	10	0
				V4 (WEEK 24)	6	-4	6	-4
				V5 (WEEK 36)	7	-3	5	-5
				V6 (WEEK 52)	7	-3	7	-3
				V7 (WEEK 56)	4	-6	4	-6
	056	75	5	SCREENING	14		14	
				V1 (WEEK 0)	15		11	

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	056	75	5	V3 (WEEK 12)				
				V4 (WEEK 24)	9	-6	9	-2
				V5 (WEEK 36)	12	-3	11	0
				V6 (WEEK 52)	11	-4	11	0
				V7 (WEEK 56)	7	-8	7	-4
	058	110	1	SCREENING	6		6	
				V1 (WEEK 0)	16		13	
				V3 (WEEK 12)	8	-8	7	-6
				V4 (WEEK 24)	8	-8	7	-6
				V5 (WEEK 36)	9	-7	7	-6
				V6 (WEEK 52)	7	-9	6	-7
				V7 (WEEK 56)	8	-8	7	-6
	059	116	1	SCREENING	7		7	
				V1 (WEEK 0)	7		7	
				V3 (WEEK 12)	10	3	10	3
				V4 (WEEK 24)	8	1	8	1
				V5 (WEEK 36)	7	0	7	0
				V6 (WEEK 52)	8	1	8	1
				V7 (WEEK 56)	7	0	7	0

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Listing 16.2.6.3: Category Fluency Test (CFT)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	065	84	16	SCREENING	4		4	
				V1 (WEEK 0)	1		1	
				V3 (WEEK 12)	8	7	8	7
				V4 (WEEK 24)	6	5	5	4
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	068	85	16	SCREENING	12		11	
				V1 (WEEK 0)	11		11	
				V3 (WEEK 12)	15	4	15	4
				V4 (WEEK 24)	11	0	10	-1
				V5 (WEEK 36)	8	-3	8	-3
				V6 (WEEK 52)	6	-5	6	-5
				V7 (WEEK 56)	7	-4	7	-4
	069	100	23	SCREENING	5		5	
				V1 (WEEK 0)	11		11	
				V3 (WEEK 12)	11	0	11	0
				V4 (WEEK 24)	9	-2	9	-2
				V5 (WEEK 36)	14	3	13	2
				V6 (WEEK 52)	10	-1	10	-1

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	069	100	23	V7 (WEEK 56)	12	1	12	1
	072	106	18	SCREENING	3		3	
				V1 (WEEK 0)	4		4	
				V3 (WEEK 12)	4	0	3	-1
				V4 (WEEK 24)	3	-1	3	-1
				V5 (WEEK 36)	4	0	4	0
				V6 (WEEK 52)	3	-1	3	-1
				V7 (WEEK 56)	3	-1	3	-1
	079	57	13	SCREENING	6		6	
				V1 (WEEK 0)	1		1	
				V3 (WEEK 12)	4	3	4	3
				V4 (WEEK 24)	2	1	2	1
				V5 (WEEK 36)	4	3	4	3
				V6 (WEEK 52)	2	1	2	1
				V7 (WEEK 56)	6	5	6	5
	082	26	17	SCREENING	15		15	
				V1 (WEEK 0)	17		17	
				V3 (WEEK 12)	12	-5	12	-5
				V4 (WEEK 24)	13	-4	12	-5

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	082	26	17	V5 (WEEK 36)	12	-5	12	-5
				V6 (WEEK 52)	13	-4	13	-4
				V7 (WEEK 56)	10	-7	10	-7
	084	28	17	SCREENING	9		9	
				V1 (WEEK 0)	10		10	
				V3 (WEEK 12)	11	1	10	0
				V4 (WEEK 24)	15	5	14	4
				V5 (WEEK 36)	10	0	9	-1
				V6 (WEEK 52)	9	-1	9	-1
				V7 (WEEK 56)	9	-1	8	-2
	086	112	21	SCREENING	13		13	
				V1 (WEEK 0)	11		11	
				V3 (WEEK 12)	11	0	11	0
				V4 (WEEK 24)	14	3	14	3
				V5 (WEEK 36)	9	-2	8	-3
				V6 (WEEK 52)	10	-1	10	-1
				V7 (WEEK 56)	11	0	11	0
	088	40	16	SCREENING	12		12	
				V1 (WEEK 0)	8		8	

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Listing 16.2.6.3: Category Fluency Test (CFT)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Words Generated		Words Acceptable	
					Total	Difference From Baseline	Total	Difference From Baseline
Placebo	088	40	16	V3 (WEEK 12)	11	3	9	1
				V4 (WEEK 24)	7	-1	7	-1
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	002	46	1	SCREENING	31		205	
				V1 (WEEK 0)	21		136	
				V3 (WEEK 12)	36	15	189	53
				V4 (WEEK 24)	35	14	157	21
				V5 (WEEK 36)	51	30	133	-3
				V6 (WEEK 52)	48	27	300	164
				V7 (WEEK 56)	35	14	190	54
	004	47	1	SCREENING	102		208	
				V1 (WEEK 0)	80		205	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	006	8	2	SCREENING	30		235	
				V1 (WEEK 0)	61		125	
				V3 (WEEK 12)	61	0	194	69
				V4 (WEEK 24)	43	-18	239	114
				V5 (WEEK 36)	47	-14	300	175
				V6 (WEEK 52)	58	-3	258	133

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	006	8	2	V7 (WEEK 56)	102	41	271	146
	010	10	1	SCREENING	70		296	
				V1 (WEEK 0)	74		255	
				V3 (WEEK 12)	65	-9		
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	012	67	1	SCREENING	67			
				V1 (WEEK 0)	126		239	
				V3 (WEEK 12)	70	-56	216	-23
				V4 (WEEK 24)	60	-66	257	18
				V5 (WEEK 36)	173	47		
				V6 (WEEK 52)	62	-64	240	1
				V7 (WEEK 56)	163	37	240	1
	014	22	4	SCREENING	38		176	
				V1 (WEEK 0)	51		112	
				V3 (WEEK 12)	34	-17	71	-41
				V4 (WEEK 24)	61	10	130	18

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	014	22	4	V5 (WEEK 36)	41	-10	116	4
				V6 (WEEK 52)	35	-16	146	34
				V7 (WEEK 56)	43	-8	80	-32
	015	23	4	SCREENING	42		87	
				V1 (WEEK 0)	37		87	
				V3 (WEEK 12)	34	-3	103	16
				V4 (WEEK 24)	39	2	87	0
				V5 (WEEK 36)	50	13	150	63
				V6 (WEEK 52)	60	23	183	96
				V7 (WEEK 56)	34	-3	105	18
	017	17	5	SCREENING	40		190	
				V1 (WEEK 0)	45		160	
				V3 (WEEK 12)	65	20	205	45
				V4 (WEEK 24)	54	9	150	-10
				V5 (WEEK 36)	42	-3	200	40
				V6 (WEEK 52)	45	0	97	-63
				V7 (WEEK 56)	33	-12	105	-55
	019	19	5	SCREENING	40		90	
				V1 (WEEK 0)	40		80	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	019	19	5	V3 (WEEK 12)	31	-9	89	9
				V4 (WEEK 24)	45	5	99	19
				V5 (WEEK 36)	40	0	84	4
				V6 (WEEK 52)	81	41	139	59
				V7 (WEEK 56)	39	-1	70	-10
	023	71	4	SCREENING	61		286	
				V1 (WEEK 0)	49		242	
				V3 (WEEK 12)	118	69	300	58
				V4 (WEEK 24)	97	48		
				V5 (WEEK 36)	106	57	300	58
				V6 (WEEK 52)	180	131		
				V7 (WEEK 56)	180	131		
	027	87	20	SCREENING	74			
				V1 (WEEK 0)	113		242	
				V3 (WEEK 12)	97	-16	291	49
				V4 (WEEK 24)	80	-33		
				V5 (WEEK 36)	78	-35		
				V6 (WEEK 52)	39	-74		
				V7 (WEEK 56)	72	-41	195	-47

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	030	50	8	SCREENING	180			
				V1 (WEEK 0)	154			
				V3 (WEEK 12)	180	26		
				V4 (WEEK 24)	180	26		
				V5 (WEEK 36)	180	26		
				V6 (WEEK 52)				
				V7 (WEEK 56)	180	26		
	032	52	8	SCREENING	71		270	
				V1 (WEEK 0)	56		157	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	033	33	9	SCREENING	180			
				V1 (WEEK 0)	127			
				V3 (WEEK 12)	101	-26		
				V4 (WEEK 24)	108	-19		
				V5 (WEEK 36)	180	53		
				V6 (WEEK 52)	153	26		

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	033	33	9	V7 (WEEK 56)	125	-2		
	042	70	12	SCREENING	170		300	
				V1 (WEEK 0)	180		300	
				V3 (WEEK 12)	180	0	300	0
				V4 (WEEK 24)	180	0	300	0
				V5 (WEEK 36)	180	0	300	0
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	043	43	12	SCREENING	180		300	
				V1 (WEEK 0)	112		300	
				V3 (WEEK 12)	180	68	300	0
				V4 (WEEK 24)	130	18	300	0
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	046	62	11	SCREENING	66		300	
				V1 (WEEK 0)				
				V3 (WEEK 12)	93		300	
				V4 (WEEK 24)	140		300	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	046	62	11	V5 (WEEK 36)	118		300	
				V6 (WEEK 52)	82		300	
				V7 (WEEK 56)	171		300	
	048	104	11	SCREENING	46		140	
				V1 (WEEK 0)	52		155	
				V3 (WEEK 12)	73	21	149	-6
				V4 (WEEK 24)	88	36	169	14
				V5 (WEEK 36)	67	15	121	-34
				V6 (WEEK 52)	48	-4	205	50
				V7 (WEEK 56)	78	26	179	24
	050	93	21	SCREENING	58		300	
				V1 (WEEK 0)	104		300	
				V3 (WEEK 12)	81	-23	300	0
				V4 (WEEK 24)	180	76	300	0
				V5 (WEEK 36)	180	76	300	0
				V6 (WEEK 52)	180	76	300	0
				V7 (WEEK 56)	86	-18	300	0
	052	91	21	SCREENING	107		300	
				V1 (WEEK 0)	85		300	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	052	91	21	V3 (WEEK 12)	109	24	300	0
				V4 (WEEK 24)	81	-4	300	0
				V5 (WEEK 36)	119	34	300	0
				V6 (WEEK 52)	119	34	300	0
				V7 (WEEK 56)	152	67	300	0
	055	76	5	SCREENING	175		300	
				V1 (WEEK 0)				
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	057	68	1	SCREENING				
				V1 (WEEK 0)				
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	066	83	16	SCREENING	180		300	
				V1 (WEEK 0)	180			
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	067	38	16	SCREENING	29		97	
				V1 (WEEK 0)	31		102	
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	071	105	18	SCREENING	178		300	
				V1 (WEEK 0)	180		300	
				V3 (WEEK 12)	180	0	300	0
				V4 (WEEK 24)	180	0	300	0
				V5 (WEEK 36)	180	0	300	0
				V6 (WEEK 52)				

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	071	105	18	V7 (WEEK 56)	180	0	300	0
	080	59	13	SCREENING	42		114	
				V1 (WEEK 0)	41		167	
				V3 (WEEK 12)	91	50	252	85
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	081	25	17	SCREENING	45		100	
				V1 (WEEK 0)	30		50	
				V3 (WEEK 12)	45	15	118	68
				V4 (WEEK 24)	102	72	90	40
				V5 (WEEK 36)	87	57	108	58
				V6 (WEEK 52)	150	120	170	120
				V7 (WEEK 56)	120	90	180	130
	083	27	17	SCREENING	80		120	
				V1 (WEEK 0)	80		150	
				V3 (WEEK 12)	60	-20	80	-70
				V4 (WEEK 24)	93	13	120	-30

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	083	27	17	V5 (WEEK 36)	120	40	180	30
				V6 (WEEK 52)	105	25	123	-27
				V7 (WEEK 56)	150	70	125	-25
	087	39	16	SCREENING	81		300	
				V1 (WEEK 0)	71			
				V3 (WEEK 12)	158	87	124	
				V4 (WEEK 24)	129	58	300	
				V5 (WEEK 36)	180	109	240	
				V6 (WEEK 52)	180	109		
				V7 (WEEK 56)	180	109		
		54	16	V3 (WEEK 12)	102		300	
	089	74	5	SCREENING	62		300	
				V1 (WEEK 0)	69			
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)	180	111		
				V6 (WEEK 52)				
				V7 (WEEK 56)	180	111		
	093	29	17	SCREENING	100		100	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
ACI-91	093	29	17	V1 (WEEK 0)	80		112	
				V3 (WEEK 12)	81	1	100	-12
				V4 (WEEK 24)	100	20	120	8
				V5 (WEEK 36)	112	32	150	38
				V6 (WEEK 52)	130	50	50	-62
				V7 (WEEK 56)	180	100	100	-12
	097	69	12	SCREENING	180		300	
				V1 (WEEK 0)				
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
Placebo	001	48	1	SCREENING	180			
				V1 (WEEK 0)	165		165	
				V3 (WEEK 12)	180	15		
				V4 (WEEK 24)				
				V5 (WEEK 36)	180	15		
				V6 (WEEK 52)				
				V7 (WEEK 56)				

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	003	45	1	SCREENING				
				V1 (WEEK 0)	180		240	
				V3 (WEEK 12)	180	0		
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	005	5	2	SCREENING	45		180	
				V1 (WEEK 0)	60		210	
				V3 (WEEK 12)	40	-20	150	-60
				V4 (WEEK 24)	65	5	175	-35
				V5 (WEEK 36)	65	5	195	-15
				V6 (WEEK 52)	65	5	172	-38
				V7 (WEEK 56)	63	3	181	-29
	009	11	1	SCREENING	74			
				V1 (WEEK 0)	99			
				V3 (WEEK 12)	94	-5	248	
				V4 (WEEK 24)	104	5	274	
				V5 (WEEK 36)	91	-8		
				V6 (WEEK 52)	87	-12		

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	009	11	1	V7 (WEEK 56)	132	33		
	011	65	1	SCREENING	47		270	
				V1 (WEEK 0)	57		267	
				V3 (WEEK 12)	69	12	274	7
				V4 (WEEK 24)	80	23		
				V5 (WEEK 36)	87	30		
				V6 (WEEK 52)	58	1		
				V7 (WEEK 56)	80	23		
	013	21	4	SCREENING	38		133	
				V1 (WEEK 0)	62		131	
				V3 (WEEK 12)	50	-12	136	5
				V4 (WEEK 24)	62	0	123	-8
				V5 (WEEK 36)	67	5	122	-9
				V6 (WEEK 52)	87	25	172	41
				V7 (WEEK 56)	57	-5	123	-8
	016	24	4	SCREENING	31		89	
				V1 (WEEK 0)	31		153	
				V3 (WEEK 12)	30	-1	75	-78
				V4 (WEEK 24)	25	-6	94	-59

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	016	24	4	V5 (WEEK 36)	39	8	97	-56
				V6 (WEEK 52)	52	21	159	6
				V7 (WEEK 56)	48	17	137	-16
	018	18	5	SCREENING	180		300	
				V1 (WEEK 0)	180			
				V3 (WEEK 12)	180	0		
				V4 (WEEK 24)	180	0		
				V5 (WEEK 36)	180	0		
				V6 (WEEK 52)	180	0		
				V7 (WEEK 56)	180	0		
	020	20	5	SCREENING	180			
				V1 (WEEK 0)	180			
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
	024	72	4	SCREENING	92		238	
				V1 (WEEK 0)	129		300	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	024	72	4	V3 (WEEK 12)	134	5	300	0
				V4 (WEEK 24)	118	-11	300	0
				V5 (WEEK 36)	160	31	300	0
				V6 (WEEK 52)	171	42	300	0
				V7 (WEEK 56)	147	18	283	-17
	028	88	20	SCREENING	69		247	
				V1 (WEEK 0)	51		112	
				V3 (WEEK 12)	53	2	143	31
				V4 (WEEK 24)	49	-2	170	58
				V5 (WEEK 36)	54	3	118	6
				V6 (WEEK 52)	58	7	182	70
				V7 (WEEK 56)	65	14	127	15
	029	49	8	SCREENING	112		300	
				V1 (WEEK 0)	91		300	
				V3 (WEEK 12)	55	-36	281	-19
				V4 (WEEK 24)	60	-31	192	-108
				V5 (WEEK 36)	148	57	300	0
				V6 (WEEK 52)	61	-30	300	0
				V7 (WEEK 56)	70	-21	300	0

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	031	51	8	SCREENING	38		170	
				V1 (WEEK 0)	42		125	
				V3 (WEEK 12)	38	-4	108	-17
				V4 (WEEK 24)	33	-9	126	1
				V5 (WEEK 36)	33	-9	166	41
				V6 (WEEK 52)	32	-10	157	32
				V7 (WEEK 56)	35	-7	136	11
	034	34	9	SCREENING	180			
				V1 (WEEK 0)				
				V3 (WEEK 12)	180			
				V4 (WEEK 24)	180			
				V5 (WEEK 36)	180			
				V6 (WEEK 52)				
				V7 (WEEK 56)	180			
	041	41	12	SCREENING	47		180	
				V1 (WEEK 0)	70		300	
				V3 (WEEK 12)	55	-15	275	-25
				V4 (WEEK 24)	91	21	115	-185
				V5 (WEEK 36)	37	-33	300	0
				V6 (WEEK 52)	68	-2	115	-185

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	041	41	12	V7 (WEEK 56)	33	-37	173	-127
	044	44	12	SCREENING	75		300	
				V1 (WEEK 0)	65		245	
				V3 (WEEK 12)	115	50	300	55
				V4 (WEEK 24)	169	104	300	55
				V5 (WEEK 36)	120	55	300	55
				V6 (WEEK 52)	116	51	300	55
				V7 (WEEK 56)	112	47	300	55
	045	61	11	SCREENING	54		240	
				V1 (WEEK 0)	85		214	
				V3 (WEEK 12)	96	11	209	-5
				V4 (WEEK 24)	95	10	210	-4
				V5 (WEEK 36)	92	7	241	27
				V6 (WEEK 52)	137	52	300	86
				V7 (WEEK 56)	158	73	300	86
	047	64	11	SCREENING	53		115	
				V1 (WEEK 0)	54		120	
				V3 (WEEK 12)	57	3	126	6
				V4 (WEEK 24)	49	-5	125	5

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	047	64	11	V5 (WEEK 36)	42	-12	133	13
				V6 (WEEK 52)	36	-18	124	4
				V7 (WEEK 56)	39	-15	112	-8
	049	90	21	SCREENING	110		180	
				V1 (WEEK 0)	179		300	
				V3 (WEEK 12)	168	-11	300	0
				V4 (WEEK 24)	138	-41	300	0
				V5 (WEEK 36)	146	-33	300	0
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	051	92	21	SCREENING	34		108	
				V1 (WEEK 0)	48		146	
				V3 (WEEK 12)	42	-6	151	5
				V4 (WEEK 24)	47	-1	160	14
				V5 (WEEK 36)	40	-8	201	55
				V6 (WEEK 52)	39	-9	178	32
				V7 (WEEK 56)	39	-9	166	20
	056	75	5	SCREENING	58		210	
				V1 (WEEK 0)	54		95	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	056	75	5	V3 (WEEK 12)				
				V4 (WEEK 24)	51	-3	142	47
				V5 (WEEK 36)	37	-17	101	6
				V6 (WEEK 52)	48	-6	113	18
				V7 (WEEK 56)	46	-8	141	46
	058	110	1	SCREENING	87		300	
				V1 (WEEK 0)	71		238	
				V3 (WEEK 12)	89	18	239	1
				V4 (WEEK 24)	97	26		
				V5 (WEEK 36)	53	-18	231	-7
				V6 (WEEK 52)	51	-20		
				V7 (WEEK 56)	70	-1		
	059	116	1	SCREENING	79		236	
				V1 (WEEK 0)	69		283	
				V3 (WEEK 12)	83	14	300	17
				V4 (WEEK 24)	140	71	240	-43
				V5 (WEEK 36)	116	47	240	-43
				V6 (WEEK 52)	97	28	240	-43
				V7 (WEEK 56)	131	62		

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	065	84	16	SCREENING	50		255	
				V1 (WEEK 0)	65			
				V3 (WEEK 12)	50	-15	199	
				V4 (WEEK 24)	58	-7	300	
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	068	85	16	SCREENING	69		134	
				V1 (WEEK 0)	53		118	
				V3 (WEEK 12)	120	67	140	22
				V4 (WEEK 24)	63	10	116	-2
				V5 (WEEK 36)	80	27	170	52
				V6 (WEEK 52)	82	29	165	47
				V7 (WEEK 56)	79	26	177	59
	069	100	23	SCREENING	73			
				V1 (WEEK 0)	65			
				V3 (WEEK 12)	61	-4	182	
				V4 (WEEK 24)	58	-7	284	
				V5 (WEEK 36)	75	10		
				V6 (WEEK 52)	51	-14	300	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	069	100	23	V7 (WEEK 56)	60	-5	197	
	072	106	18	SCREENING	118		153	
				V1 (WEEK 0)	162		300	
				V3 (WEEK 12)	174	12	300	0
				V4 (WEEK 24)	180	18	300	0
				V5 (WEEK 36)	180	18	300	0
				V6 (WEEK 52)	180	18	300	0
				V7 (WEEK 56)	176	14	300	0
	079	57	13	SCREENING				
				V1 (WEEK 0)				
				V3 (WEEK 12)				
				V4 (WEEK 24)				
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				
	082	26	17	SCREENING	45		110	
				V1 (WEEK 0)	25		60	
				V3 (WEEK 12)	32	7	98	38
				V4 (WEEK 24)	50	25	120	60

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	082	26	17	V5 (WEEK 36)	55	30	110	50
				V6 (WEEK 52)	68	43	102	42
				V7 (WEEK 56)	80	55	95	35
	084	28	17	SCREENING	65		111	
				V1 (WEEK 0)	55		112	
				V3 (WEEK 12)	55	0	120	8
				V4 (WEEK 24)	100	45	112	0
				V5 (WEEK 36)	91	36	175	63
				V6 (WEEK 52)	115	60	123	11
				V7 (WEEK 56)	95	40	143	31
	086	112	21	SCREENING	147		300	
				V1 (WEEK 0)	107		199	
				V3 (WEEK 12)	146	39	295	96
				V4 (WEEK 24)	173	66	292	93
				V5 (WEEK 36)	112	5	192	-7
				V6 (WEEK 52)	179	72	300	101
				V7 (WEEK 56)	148	41	285	86
	088	40	16	SCREENING	56			
				V1 (WEEK 0)	43		70	

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Listing 16.2.6.4: Trail Making Tests A (TMA) and B (TMB)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Trails A		Trails B	
					Derived Upper Limit	Difference From Baseline	Derived Upper Limit	Difference From Baseline
Placebo	088	40	16	V3 (WEEK 12)	58	15	300	230
				V4 (WEEK 24)	70	27		
				V5 (WEEK 36)				
				V6 (WEEK 52)				
				V7 (WEEK 56)				

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	002	1	SCREENING	2009-04-16	11:50	1	32		
						2	32	411	176
			V1 (WEEK 0)	2009-04-23	9:50	1	32		
						2	32	414	77
			V3 (WEEK 12)	2009-07-16	9:47	1	32		
						2	32	313	64
			V4 (WEEK 24)	2009-10-08	10:02	1	32		
						2	32	398	200
			V5 (WEEK 36)	2010-01-05	10:59	1	32		
						2	32	626	283
			V6 (WEEK 52)	2010-04-22	9:40	1	32		
						2	32	530	148
			V7 (WEEK 56)	2010-05-20	10:19	1	32		
						2	32	492	231
	004	1	SCREENING	2009-06-22	8:40	1	32		
						2	32	452	189
			V1 (WEEK 0)	2009-07-16	11:03	1	32		
						2	32	351	196
	006	2	SCREENING	2010-01-25	10:43	1	32		
						2	32	305	92
			V3 (WEEK 12)	2010-05-21	11:37	1	32		
						2	32	369	85
			V4 (WEEK 24)	2010-08-13	12:49	1	32		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	006	2	V4 (WEEK 24)	2010-08-13	12:49	2	32	499	220
			V5 (WEEK 36)	2010-11-04	10:26	1	32		
						2	32	585	398
			V6 (WEEK 52)	2011-02-24	11:58	1	32		
						2	32	532	278
			V7 (WEEK 56)	2011-03-22	10:40	1	34		
						2	32	620	477
	010	1	SCREENING	2009-06-25	11:44	1	32		
						2	32	572	252
			V1 (WEEK 0)	2009-07-21	11:19	1	32		
						2	32	371	125
	012	1	V3 (WEEK 12)	2009-10-13	10:08	1	32		
						2	32	690	721
			SCREENING	2010-06-17	13:41	1	32		
						2	32	674	335
	014	4	V1 (WEEK 0)	2010-07-19	10:39	1	32		
						2	32	538	213
			SCREENING	2009-10-07	12:54	1	33		
						2	32	296	63
			V1 (WEEK 0)	2009-11-02	11:09	1	32		
						2	32	353	232
			V3 (WEEK 12)	2010-01-25	10:36	1	32		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	014	4	V3 (WEEK 12)	2010-01-25	10:36	2	32	408	540
			V4 (WEEK 24)	2010-04-22	12:04	1	32		
						2	32	310	137
			V5 (WEEK 36)	2010-07-15	11:24	1	32		
						2	32	411	401
			V6 (WEEK 52)	2010-10-28	13:28	1	34		
						2	32	474	488
			V7 (WEEK 56)	2010-12-02	12:31	1	32		
						2	32	428	613
	015	4	SCREENING	2010-01-21	12:06	1	33		
						2	32	411	222
			V1 (WEEK 0)	2010-02-22	10:44	1	32		
						2	32	456	131
			V3 (WEEK 12)	2010-05-17	10:56	1	32		
						2	32	496	565
			V4 (WEEK 24)	2010-08-02	10:44	1	32		
						2	32	382	85
			V5 (WEEK 36)	2010-10-27	11:01	1	33		
						2	32	773	652
			V6 (WEEK 52)	2011-02-21	13:31	1	32		
						2	32	428	68
			V7 (WEEK 56)	2011-03-22	11:16	1	32		
						2	32	346	201

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	017	5	SCREENING	2009-07-14	11:22	1	33		
						2	32	512	275
			V1 (WEEK 0)	2009-08-05	10:07	1	32		
						2	32	366	148
			V3 (WEEK 12)	2009-10-28	12:51	1	32		
						2	32	433	320
			V4 (WEEK 24)	2010-01-20	11:31	1	32		
						2	32	776	552
	019	5	V5 (WEEK 36)	2010-04-13	11:40	1	33		
						2	32	453	227
			V6 (WEEK 52)	2010-08-03	10:53	1	33		
						2	32	564	462
			V7 (WEEK 56)	2010-08-31	11:32	1	32		
						2	32	543	452
			SCREENING	2009-11-18	11:13	1	32		
						2	32	372	170
			V1 (WEEK 0)	2009-12-09	11:09	1	32		
						2	32	373	81
			V3 (WEEK 12)	2010-03-03	10:14	1	32		
						2	32	342	107
			V4 (WEEK 24)	2010-05-25	10:15	1	32		
						2	32	363	62
			V5 (WEEK 36)	2010-08-24	12:23	1	32		
						2	32	411	167

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	019	5	V6 (WEEK 52)	2010-12-07	11:19	1	32		
						2	32	425	171
			V7 (WEEK 56)	2011-01-11	11:05	1	33		
						2	32	321	76
	023	4	SCREENING	2010-07-01	14:14	1	33		
						2	32	319	86
			V3 (WEEK 12)	2010-10-13	11:49	1	32		
						2	32	542	166
			V4 (WEEK 24)	2011-01-12	12:12	1	33		
						2	32	576	192
			V5 (WEEK 36)	2011-03-21	11:14	1	34		
						2	32	659	415
			V6 (WEEK 52)	2011-07-18	11:55	1	39		
						2	32	862	709
			V7 (WEEK 56)	2011-08-11	12:26	1	32		
						2	32	686	503
	027	20	SCREENING	2010-09-30		1	33		
						2	32	334	337
			V1 (WEEK 0)	2010-10-21	10:43	1	33		
						2	32	327	176
			V3 (WEEK 12)	2011-01-20	11:56	1	34		
						2	32	635	592
			V4 (WEEK 24)	2011-04-12	12:31	1	32		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	027	20	V4 (WEEK 24)	2011-04-12	12:31	2	32	493	370
			V5 (WEEK 36)	2011-07-06	10:54	1	32		
						2	32	285	127
			V6 (WEEK 52)	2011-10-25	9:00	1	34		
						2	32	328	183
			V7 (WEEK 56)	2011-12-01	11:00	1	33		
						2	32	304	202
	030	8	SCREENING	2010-03-18	11:21	1	32		
						2	32	444	220
			V1 (WEEK 0)	2010-03-25	11:03	1	32		
						2	32	406	391
			V3 (WEEK 12)	2010-06-17	11:19	1	32		
						2	32	564	191
			V4 (WEEK 24)	2010-09-03	11:40	1	35		
						2	32	1236	940
			V5 (WEEK 36)	2010-12-02	11:22	1	32		
						2	32	674	364
			V6 (WEEK 52)	2011-03-14	11:01	1	32		
						2	32	943	572
			V7 (WEEK 56)	2011-04-11	11:09	1	32		
						2	32	736	581
	032	8	SCREENING	2010-11-08	10:40	1	32		
						2	32	427	495

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	032	8	V1 (WEEK 0)	2010-11-18	10:40	1	32		
						2	32	334	84
	033	9	SCREENING	2009-10-28	10:14	1	32		
						2	32	668	449
			V1 (WEEK 0)	2009-11-04	10:19	1	32		
						2	32	516	165
			V3 (WEEK 12)	2010-01-20	10:29	1	51		
						2	32	1064	917
			V4 (WEEK 24)	2010-04-21	13:20	1	32		
						2	32	668	494
			V5 (WEEK 36)	2010-07-22	9:28	1	33		
						2	32	918	521
			V6 (WEEK 52)	2010-11-10	10:19	1	35		
						2	32	1136	544
			V7 (WEEK 56)	2010-12-06	10:00	1	33		
						2	32	934	627
	042	12	SCREENING	2009-12-16	11:56	1	48		
						2	32	1445	985
			V1 (WEEK 0)	2010-01-14	13:35	1	37		
						2	32	1457	797
			V3 (WEEK 12)	2010-05-19	12:59	1	34		
						2	32	1493	921
			V4 (WEEK 24)	2010-06-30	11:34	1	35		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	042	12	V4 (WEEK 24)	2010-06-30	11:34	2	32	1228	830
			V5 (WEEK 36)	2010-09-22	9:47	1	43		
						2	32	1097	827
			V6 (WEEK 52)	2011-01-12	9:10	1	37		
						2	32	1381	884
			V7 (WEEK 56)	2011-02-08	9:29	1	34		
						2	32	1132	740
	043	12	SCREENING	2009-10-21	12:17	1	33		
						2	32	588	382
			V1 (WEEK 0)	2009-11-18	11:07	1	33		
						2	32	645	451
			V3 (WEEK 12)	2010-02-10	12:26	1	33		
						2	32	899	675
			V4 (WEEK 24)	2010-05-12	11:29	1	32		
						2	32	994	758
	046	11	SCREENING	2009-12-14	14:29	1	36		
						2	32	713	703
			V1 (WEEK 0)	2010-01-11	15:13	1	34		
						2	32	837	805
			V3 (WEEK 12)	2010-04-07	10:35	1	35		
						2	32	582	353
			V4 (WEEK 24)	2010-07-07	10:35	1	32		
						2	32	397	140

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	046	11	V5 (WEEK 36)	2010-09-22	12:42	1	34		
						2	32	624	514
			V6 (WEEK 52)	2011-01-12	9:39	1	34		
						2	32	429	354
		11	V7 (WEEK 56)	2011-02-07	12:00	1	36		
						2	32	726	330
		048	SCREENING	2010-11-17	12:44	1	32		
						2	32	399	66
			V1 (WEEK 0)	2010-11-22	14:56	1	32		
						2	32	300	76
			V3 (WEEK 12)	2011-02-15	12:20	1	32		
						2	32	299	84
			V4 (WEEK 24)	2011-05-16	13:22	1	32		
						2	32	349	78
		050	V5 (WEEK 36)	2011-07-26	13:06	1	32		
						2	32	338	54
			V6 (WEEK 52)	2011-11-16	15:15	1	32		
						2	32	456	141
			V7 (WEEK 56)	2011-12-21	13:40	1	32		
						2	32	336	91
		21	SCREENING	2010-09-06	13:30	1	33		
						2	32	961	635
			V1 (WEEK 0)	2010-10-27	13:00	1	33		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	050	21	V1 (WEEK 0)	2010-10-27	13:00	2	32	625	220
			V3 (WEEK 12)	2011-01-17	13:12	1	38		
						2	32	1262	806
			V4 (WEEK 24)	2011-04-11	12:34	1	32		
						2	32	1047	480
			V5 (WEEK 36)	2011-07-04	12:46	1	32		
						2	32	1044	570
			V6 (WEEK 52)	2011-10-24	10:09	1	35		
	052	21	V7 (WEEK 56)	2011-11-21	9:34	2	32	1216	785
						1	33		
						2	32	1385	966
			SCREENING	2010-09-06	17:43	1	32		
						2	32	716	525
			V1 (WEEK 0)	2010-10-28	10:58	1	36		
						2	32	1218	824
			V3 (WEEK 12)	2011-01-17	9:21	1	43		
						2	32	1752	980
			V4 (WEEK 24)	2011-04-11	9:14	1	33		
						2	32	1895	782
			V5 (WEEK 36)	2011-07-04	10:30	1	37		
						2	32	1846	752
			V6 (WEEK 52)	2011-10-24	13:32	1	34		
						2	32	1217	710
			V7 (WEEK 56)	2011-11-21	10:58	1	34		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	052	21	V7 (WEEK 56)	2011-11-21	10:58	2	32	1329	811
	055	5	SCREENING	2010-03-08	10:51	1	33		
						2	32	402	345
				2010-03-29	11:33	1	33		
						2	32	317	96
	066	16	SCREENING	2010-08-09	13:17	1	35		
						2	32	752	367
				2010-09-13	10:11	1	35		
						2	32	785	640
	067	16	SCREENING	2010-11-02	11:39	1	32		
						2	32	323	46
				2010-11-18	11:09	1	32		
						2	32	356	108
	071	18	SCREENING	2010-10-20	0:30	1	33		
						2	32	1297	517
				2011-07-19	10:37	1	88		
						2	17	1198	883
				2011-11-17	12:28	1	47		
						2	32	831	533
				2011-12-05	12:58	1	96		
						2	10	1238	1236

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	080	13	SCREENING	2010-11-15	10:01	1	32		
						2	32	573	138
			V1 (WEEK 0)	2010-11-18	10:38	1	32		
						2	32	412	248
			V3 (WEEK 12)	2011-02-09	10:04	1	32		
	081	17				2	32	571	178
			SCREENING	2010-10-04	13:09	1	34		
						2	32	499	215
			V1 (WEEK 0)	2010-10-14	21:51	1	49		
						2	32	1294	1057
			V3 (WEEK 12)	2011-01-10	21:51	1	49		
						2	32	1294	1057
			V4 (WEEK 24)	2011-04-06	12:46	1	35		
						2	32	825	797
			V5 (WEEK 36)	2011-06-20		1	38		
						2	32	2105	996
			V6 (WEEK 52)	2011-10-24		1	50		
						2	32	1802	1192
			V7 (WEEK 56)	2011-11-22		1	58		
						2	32	2276	1087
	083	17	SCREENING	2010-10-26	10:04	1	42		
						2	32	1182	978
			V1 (WEEK 0)	2010-11-10	10:08	1	38		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	083	17	V1 (WEEK 0)	2010-11-10	10:08	2	32	1447	996
			V3 (WEEK 12)	2011-02-02	10:08	1	38		
						2	32	1447	996
			V4 (WEEK 24)	2011-04-26	10:08	1	38		
						2	32	1447	996
			V5 (WEEK 36)	2010-07-25		1	37		
						2	32	2022	987
			V6 (WEEK 52)	2011-11-09		1	39		
						2	32	1515	870
			V7 (WEEK 56)	2011-12-06		1	43		
						2	32	2569	1044
	087	16	SCREENING	2010-11-09	10:35	1	32		
						2	32	644	238
			V1 (WEEK 0)	2010-11-29	9:00	1	33		
						2	32	381	143
			V3 (WEEK 12)	2011-02-17	11:04	1	32		
						2	32	733	220
			V4 (WEEK 24)	2011-03-07	10:47	1	32		
						2	32	744	309
			V5 (WEEK 36)	2011-08-10	12:29	1	32		
						2	32	610	522
			V6 (WEEK 52)	2011-11-28	11:56	1	32		
						2	32	852	536
			V7 (WEEK 56)	2011-12-28	11:02	1	32		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	087	16	V7 (WEEK 56)	2011-12-28	11:02	2	32	810	536
	089	5	V1 (WEEK 0)	2010-11-16	11:03	1	33		
						2	32	1687	564
			V3 (WEEK 12)	2011-02-07	11:15	1	36		
						2	32	1099	887
	093	17	SCREENING	2010-11-29	9:05	1	33		
						2	32	363	80
			V1 (WEEK 0)	2010-12-02	12:31	1	62		
						2	32	1634	1122
			V3 (WEEK 12)	2011-02-25	14:48	1	53		
						2	32	1528	845
			V4 (WEEK 24)	2011-05-23	14:51	1	43		
						2	32	1064	814
			V5 (WEEK 36)	2011-08-16		1	66		
						2	32	2123	1062
			V6 (WEEK 52)	2011-12-06		1	82		
						2	32	2053	1078
			V7 (WEEK 56)	2011-12-28		1	49		
						2	32	2153	947
	097	12	SCREENING	2010-10-27	12:06	1	34		
						2	32	932	666
			V1 (WEEK 0)	2010-11-17	9:24	1	36		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	097	12	V1 (WEEK 0)	2010-11-17	9:24	2	32	695	411
			V3 (WEEK 12)	2011-02-09	9:42	1	39		
						2	32	1200	806
Placebo	001	1	SCREENING	2009-04-02	9:43	1	37		
						2	32	1097	442
			V1 (WEEK 0)	2009-04-09	9:21	1	32		
						2	32	611	275
			V3 (WEEK 12)	2009-07-07	10:01	1	37		
						2	32	776	403
			V4 (WEEK 24)	2009-09-17	10:06	1	37		
						2	32	1122	760
			V5 (WEEK 36)	2009-12-10	11:38	1	32		
						2	32	754	443
	003	1	SCREENING	2009-05-07	9:57	1	32		
						2	32	1136	515
	005	2	SCREENING	2009-05-19	15:43	1	32		
						2	32	373	109
			V1 (WEEK 0)	2009-06-04	10:07	1	33		
						2	32	336	46
			V3 (WEEK 12)	2009-08-25	9:58	1	32		
						2	32	430	66
			V4 (WEEK 24)	2009-11-18	11:54	1	32		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	005	2	V4 (WEEK 24)	2009-11-18	11:54	2	32	652	324
			V5 (WEEK 36)	2010-02-16	11:46	1	32		
						2	32	418	90
			V6 (WEEK 52)	2010-06-02	12:01	1	34		
						2	32	444	70
			V7 (WEEK 56)	2010-07-08	9:47	1	32		
						2	32	377	63
	009	1	SCREENING	2009-08-06	12:22	1	32		
						2	32	442	298
			V1 (WEEK 0)	2009-09-08	10:03	1	39		
						2	32	837	466
			V3 (WEEK 12)	2009-12-10	10:37	1	33		
						2	32	543	299
			V4 (WEEK 24)	2010-03-04	11:49	1	33		
						2	32	527	179
			V5 (WEEK 36)	2010-05-11	9:33	1	33		
						2	32	474	274
			V6 (WEEK 52)	2010-09-03	12:18	1	33		
						2	32	644	375
	011	1	SCREENING	2009-11-05	14:26	1	32		
						2	32	638	195
			V1 (WEEK 0)	2009-11-26	9:48	1	32		
						2	32	391	194

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	011	1	V3 (WEEK 12)	2010-02-18	10:02	1	32		
						2	32	553	205
			V4 (WEEK 24)	2010-05-06	13:02	1	32		
						2	32	490	560
			V5 (WEEK 36)	2010-08-05	15:27	1	32		
						2	32	608	191
	013	4	SCREENING	2009-08-17	11:29	1	34		
						2	32	506	205
			V1 (WEEK 0)	2009-09-16	10:50	1	32		
						2	32	378	142
			V3 (WEEK 12)	2009-12-09	10:57	1	33		
						2	32	352	122
			V4 (WEEK 24)	2010-03-04	11:03	1	32		
						2	32	312	108
			V5 (WEEK 36)	2010-05-20	11:20	1	32		
						2	32	344	424
			V6 (WEEK 52)	2010-09-16	12:24	1	32		
						2	32	349	145
	016	4	SCREENING	2010-02-01	11:27	1	32		
						2	32	290	229
			V1 (WEEK 0)	2010-03-01	10:48	1	32		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	016	4	V1 (WEEK 0)	2010-03-01	10:48	2	32	269	216
			V3 (WEEK 12)	2010-05-19	10:11	1	32		
						2	32	247	98
			V4 (WEEK 24)	2010-08-09	11:30	1	32		
						2	32	362	489
			V5 (WEEK 36)	2010-11-08	10:55	1	32		
						2	32	356	265
	018	5	V6 (WEEK 52)	2011-02-28	11:50	1	32		
						2	32	367	389
			V7 (WEEK 56)	2011-04-07	12:39	1	33		
						2	32	459	143
			SCREENING	2009-11-03	12:45	1	32		
						2	32	407	152
			V1 (WEEK 0)	2009-11-23	12:17	1	37		
						2	32	478	537
			V3 (WEEK 12)	2010-02-16	11:33	1	34		
						2	32	322	128
			V4 (WEEK 24)	2010-05-11	11:46	1	36		
						2	32	419	239
			V5 (WEEK 36)	2010-07-27	10:13	1	39		
						2	32	336	138
			V6 (WEEK 52)	2010-11-23	11:56	1	35		
						2	32	675	437
			V7 (WEEK 56)	2010-12-14	10:53	1	34		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	018	5	V7 (WEEK 56)	2010-12-14	10:53	2	32	792	795
	020	5	SCREENING	2010-01-27	17:22	1	36	1711	1046
						2	32		
						1	63		
			V1 (WEEK 0)	2010-02-22	12:46	2	32	1907	984
	024	4	SCREENING	2010-07-16	11:34	1	32	437	124
						2	32		
			V1 (WEEK 0)	2010-08-16	10:45	1	32	427	94
						2	32		
			V3 (WEEK 12)	2010-11-10	12:21	1	33	469	135
						2	32		
			V4 (WEEK 24)	2011-02-02	11:13	1	33	465	114
						2	32		
			V5 (WEEK 36)	2011-04-18	11:03	1	32	598	257
						2	32		
	028	20	SCREENING	2010-11-18	11:41	1	32	539	121
						2	32		
			V1 (WEEK 0)	2010-11-26	10:11	1	32	415	156
			V3 (WEEK 12)	2011-02-22	11:14	1	35		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	028	20	V3 (WEEK 12)	2011-02-22	11:14	2	32	569	346
			V4 (WEEK 24)	2011-05-24	11:51	1	32		
						2	32	683	277
			V5 (WEEK 36)	2011-08-25	14:37	1	32		
						2	32	352	81
			V6 (WEEK 52)	2011-11-24	9:29	1	32		
						2	32	620	274
			V7 (WEEK 56)	2011-12-20	9:34	1	32		
						2	32	453	210
	029	8	SCREENING	2010-01-26	11:00	1	38		
						2	32	341	181
			V1 (WEEK 0)	2010-01-29	11:22	1	32		
						2	32	422	204
			V4 (WEEK 24)	2010-07-05	10:27	1	32		
						2	32	433	75
			V5 (WEEK 36)	2010-09-30	10:45	1	32		
						2	32	355	116
			V6 (WEEK 52)	2011-02-01	10:39	1	32		
						2	32	531	296
	031	8	SCREENING	2010-05-06	12:46	1	32		
						2	32	359	126

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	031	8	V1 (WEEK 0)	2010-05-20	10:44	1	32		
						2	32	255	76
			V3 (WEEK 12)	2010-08-17	11:19	1	33		
						2	32	228	43
			V4 (WEEK 24)	2010-11-09	10:05	1	32		
						2	32	370	104
			V5 (WEEK 36)	2011-01-25	10:36	1	32		
						2	32	347	275
	041	12	V6 (WEEK 52)	2011-05-17	12:44	1	32		
						2	32	307	98
			V7 (WEEK 56)	2011-06-14	11:05	1	32		
						2	32	251	68
			SCREENING	2009-09-23	12:17	1	33		
						2	32	912	702
			V1 (WEEK 0)	2009-10-09	14:34	1	32		
						2	32	461	399
			V3 (WEEK 12)	2010-01-05	14:26	1	33		
						2	32	429	203
			V4 (WEEK 24)	2010-03-24	12:03	1	32		
						2	32	486	465
			V5 (WEEK 36)	2010-06-16	10:21	1	32		
						2	32	503	472
			V6 (WEEK 52)	2010-10-06	10:43	1	32		
						2	32	384	371

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	041	12	V7 (WEEK 56)	2010-11-03	9:18	1	32		
						2	32	361	256
	044	12	SCREENING	2009-11-04	11:39	1	32		
						2	32	314	122
			V1 (WEEK 0)	2009-12-02	11:07	1	33		
						2	32	378	92
			V3 (WEEK 12)	2010-02-24	12:01	1	32		
						2	32	571	369
			V4 (WEEK 24)	2010-05-26	10:07	1	32		
						2	32	487	430
			V5 (WEEK 36)	2010-08-18	12:19	1	33		
						2	32	819	578
			V6 (WEEK 52)	2010-12-01	10:03	1	32		
						2	32	549	264
			V7 (WEEK 56)	2011-01-05	11:53	1	34		
						2	32	547	391
	045	11	SCREENING	2009-12-07	14:44	1	32		
						2	32	508	444
			V1 (WEEK 0)	2009-12-21	13:25	1	33		
						2	32	552	494
			V3 (WEEK 12)	2010-03-15	10:54	1	33		
						2	32	461	317
			V4 (WEEK 24)	2010-06-07	12:05	1	33		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	045	11	V4 (WEEK 24)	2010-06-07	12:05	2	32	483	193
			V5 (WEEK 36)	2010-09-06	12:24	1	37		
						2	32	444	424
			V6 (WEEK 52)	2010-12-15	11:55	1	33		
						2	32	561	535
			V7 (WEEK 56)	2011-01-17	12:06	1	41		
	047	11				2	32	1380	1084
			SCREENING	2010-07-12	11:49	1	32		
						2	32	525	568
			V1 (WEEK 0)	2010-08-02	13:12	1	33		
						2	32	346	118
			V3 (WEEK 12)	2010-10-20	14:33	1	32		
						2	32	357	111
			V4 (WEEK 24)	2011-01-10	12:06	1	32		
						2	32	315	78
			V5 (WEEK 36)	2011-04-12	12:10	1	32		
						2	32	375	236
			V6 (WEEK 52)	2011-07-27	12:06	1	32		
						2	32	327	60
			V7 (WEEK 56)	2011-08-29	9:51	1	32		
	049	21	SCREENING	2010-09-06	9:37	2	32	820	277
						1	33		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	049	21	V1 (WEEK 0)	2010-10-27	10:19	1	32		
						2	32	741	605
			V3 (WEEK 12)	2011-01-18	9:26	1	32		
						2	32	475	87
			V4 (WEEK 24)	2011-04-12	9:23	1	32		
						2	32	370	94
	051	21	V5 (WEEK 36)	2011-07-05	14:21	1	32		
						2	32	408	152
			SCREENING	2010-09-06	11:35	1	32		
						2	32	755	641
			V1 (WEEK 0)	2010-10-28	13:19	1	32		
						2	32	405	140
			V3 (WEEK 12)	2011-02-01	8:51	1	32		
						2	32	413	181
			V4 (WEEK 24)	2011-04-12	14:29	1	33		
						2	32	482	291
			V5 (WEEK 36)	2011-07-05	15:36	1	32		
						2	32	546	171
			V6 (WEEK 52)	2011-10-25	10:05	1	32		
						2	32	423	144
			V7 (WEEK 56)	2011-11-22	9:08	1	32		
						2	32	426	128
	056	5	SCREENING	2010-03-31	11:55	1	32		

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	056	5	SCREENING	2010-03-31	11:55	2	32	448	294
			V1 (WEEK 0)	2010-04-21	10:36	1	32		
						2	32	394	83
			V4 (WEEK 24)	2010-10-05	11:21	1	32		
						2	32	382	187
			V5 (WEEK 36)	2011-01-04	10:51	1	32		
						2	32	407	75
			V6 (WEEK 52)	2011-04-19	10:43	1	33		
						2	32	389	112
	065	16	SCREENING	2010-08-10	12:54	1	33		
						2	32	348	98
			V1 (WEEK 0)	2010-08-30	13:22	1	42		
						2	32	1754	730
			V4 (WEEK 24)	2011-01-17	12:26	1	32		
						2	32	440	110
	068	16	SCREENING	2010-10-26	10:41	1	33		
						2	32	463	90
			V1 (WEEK 0)	2010-11-22	11:29	1	32		
						2	32	456	94
			V3 (WEEK 12)	2011-02-10	10:33	1	32		
						2	32	554	266
			V4 (WEEK 24)	2011-05-03	11:32	1	32		
						2	32	505	588

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	068	16	V5 (WEEK 36)	2011-08-10	9:51	1	33		
						2	32	618	170
			V6 (WEEK 52)	2011-11-28	13:14	1	39		
						2	32	789	360
	069	23	SCREENING	2010-11-24	10:52	1	32		
						2	32	395	384
			V1 (WEEK 0)	2010-12-07	13:40	1	32		
						2	32	469	259
			V3 (WEEK 12)	2011-03-09	11:23	1	32		
						2	32	334	128
			V4 (WEEK 24)	2011-05-19	10:45	1	32		
						2	32	425	238
			V5 (WEEK 36)	2011-08-24	11:00	1	34		
						2	32	511	276
			V6 (WEEK 52)	2011-12-14	11:03	1	34		
						2	32	430	248
	072	18	V7 (WEEK 56)	2012-01-11	11:06	1	32		
						2	32	478	332
			SCREENING	2010-12-01	0:35	1	32		
						2	32	645	326
			V1 (WEEK 0)	2010-12-21	0:31	1	40		
						2	32	1281	936
			V3 (WEEK 12)	2011-03-15	10:01	1	78		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	072	18	V3 (WEEK 12)	2011-03-15	10:01	2	32	807	609
			V4 (WEEK 24)	2011-06-07	10:53	1	52		
						2	32	1316	874
			V5 (WEEK 36)	2011-09-08	11:27	1	39		
						2	3	904	372
			V6 (WEEK 52)	2011-12-15	10:43	1	86		
						2	32	1143	1158
	079	13	V7 (WEEK 56)	2012-01-17	12:55	1	86		
						2	32	1143	1158
			SCREENING	2010-07-19	13:50	1	32		
						2	32	870	167
			V1 (WEEK 0)	2010-08-06	12:22	1	32		
						2	32	1031	344
			V3 (WEEK 12)	2010-11-16	13:19	1	32		
						2	32	1544	598
			V4 (WEEK 24)	2011-01-27	12:39	1	33		
						2	32	1343	424
			V5 (WEEK 36)	2011-04-11	13:51	1	32		
						2	32	1111	287
			V6 (WEEK 52)	2011-06-21	14:15	1	34		
						2	32	1300	361
			V7 (WEEK 56)	2011-07-19	13:08	1	33		
						2	32	1481	600

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	082	17	SCREENING	2010-10-06	20:44	1	35		
						2	32	1787	692
			V1 (WEEK 0)	2010-10-14	9:39	1	32		
						2	32	650	340
			V3 (WEEK 12)	2011-01-05	12:57	1	32		
						2	32	907	675
			V4 (WEEK 24)	2011-04-06	12:57	1	32		
						2	32	907	675
			V5 (WEEK 36)	2011-06-22		1	35		
						2	32	2284	1020
			V6 (WEEK 52)	2011-10-12		1	34		
						2	32	1337	632
			V7 (WEEK 56)	2011-11-24		1	39		
						2	32	1380	884
	084	17	SCREENING	2010-11-08	21:36	1	55		
						2	32	1859	1195
			V1 (WEEK 0)	2010-11-17	21:36	1	55		
						2	32	1859	1195
			V3 (WEEK 12)	2011-02-08	14:25	1	56		
						2	32	1364	1033
			V4 (WEEK 24)	2011-05-10	14:33	1	33		
						2	32	1143	734
			V5 (WEEK 36)	2011-08-02		1	53		
						2	32	1829	1163

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	084	17	V6 (WEEK 52)	2011-11-22		1	76		
						2	32	1832	1090
			V7 (WEEK 56)	2011-12-15		1	52		
						2	32	1977	1139
	086	21	SCREENING	2010-10-04	9:33	1	33		
						2	32	614	324
			V1 (WEEK 0)	2010-10-28	15:31	1	32		
						2	32	526	558
			V3 (WEEK 12)	2011-01-18	12:44	1	32		
						2	32	344	170
			V4 (WEEK 24)	2011-04-12	12:58	1	32		
						2	32	577	348
			V5 (WEEK 36)	2011-07-05	13:10	1	32		
						2	32	572	226
			V6 (WEEK 52)	2011-10-25	12:31	1	32		
						2	32	614	568
	088	16	V7 (WEEK 56)	2011-11-22	11:18	1	33		
						2	32	320	210
			SCREENING	2010-11-30	11:20	1	34		
						2	32	341	91
			V1 (WEEK 0)	2010-12-09	10:01	1	35		
						2	32	471	456
			V3 (WEEK 12)	2011-03-01	10:39	1	33		

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Listing 16.2.6.5: Simple Reaction Time (SRT)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	088	16	V3 (WEEK 12)	2011-03-01	10:39	2	32	477	202
			V5 (WEEK 36)	2011-08-29	10:51	1	39		
						2	32	586	358

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	002	1	SCREENING	2009-04-16	11:54	1	48		
						2	24	369	54
			V1 (WEEK 0)	2009-04-23	9:54	1	48		
						2	24	411	62
			V3 (WEEK 12)	2009-07-16	9:50	1	48		
						2	24	376	48
			V4 (WEEK 24)	2009-10-08	10:05	1	48		
						2	24	387	40
			V5 (WEEK 36)	2010-01-05	11:02	1	48		
						2	24	614	262
			V6 (WEEK 52)	2010-04-22	9:44	1	48		
						2	24	545	132
			V7 (WEEK 56)	2010-05-20	10:22	1	48		
						2	24	528	163
	004	1	SCREENING	2009-06-22	8:43	1	48		
						2	23	515	91
			V1 (WEEK 0)	2009-07-16	11:07	1	48		
						2	24	440	85
	006	2	SCREENING	2010-01-25	10:49	1	74		
						2	45	432	58
			V3 (WEEK 12)	2010-05-21	11:41	1	48		
						2	24	434	22
			V4 (WEEK 24)	2010-08-13	12:53	1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	006	2	V4 (WEEK 24)	2010-08-13	12:53	2	24	502	72
			V5 (WEEK 36)	2010-11-04	10:30	1	48		
						2	24	549	85
			V6 (WEEK 52)	2011-02-24	12:01	1	48		
						2	24	461	47
			V7 (WEEK 56)	2011-03-22	10:44	1	48		
						2	23	534	62
	010	1	SCREENING	2009-06-25	11:46	1	48		
						2	23	529	191
			V1 (WEEK 0)	2009-07-21	11:23	1	48		
						2	24	464	82
	012	1	V3 (WEEK 12)	2009-10-13	10:12	1	48		
						2	24	536	108
			SCREENING	2010-06-17	13:44	1	48		
						2	24	489	174
	014	4	V1 (WEEK 0)	2010-07-19	10:42	1	48		
						2	23	604	158
			SCREENING	2009-10-07	12:58	1	48		
						2	24	460	76
			V1 (WEEK 0)	2009-11-02	11:13	1	48		
						2	24	410	44
			V3 (WEEK 12)	2010-01-25	10:40	1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	014	4	V3 (WEEK 12)	2010-01-25	10:40	2	24	426	69
			V4 (WEEK 24)	2010-04-22	12:07	1	48		
						2	24	426	41
			V5 (WEEK 36)	2010-07-15	11:28	1	48		
						2	24	386	80
			V6 (WEEK 52)	2010-10-28	13:32	1	48		
						2	21	512	51
	015	4	V7 (WEEK 56)	2010-12-02	12:35	1	48		
						2	24	412	66
			SCREENING	2010-01-21	12:10	1	48		
						2	0		
			V1 (WEEK 0)	2010-02-22	10:47	1	48		
						2	24	466	58
			V3 (WEEK 12)	2010-05-17	11:00	1	48		
						2	0		
			V4 (WEEK 24)	2010-08-02	10:49	1			
						2			
			V5 (WEEK 36)	2010-10-27	11:06	1	48		
						2	24	495	70
			V6 (WEEK 52)	2011-02-21	13:35	1	48		
						2	0		
			V7 (WEEK 56)	2011-03-22	11:20	1	48		
						2	24	518	140

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	017	5	SCREENING	2009-07-14	11:27	1	74		
						2	55	441	54
			V1 (WEEK 0)	2009-08-05	10:13	1	74		
						2	6	455	57
			V3 (WEEK 12)	2009-10-28	12:56	1	48		
						2	22	490	155
			V4 (WEEK 24)	2010-01-20	11:38	1	48		
						2	22	490	155
	019	5	V5 (WEEK 36)	2010-04-13	11:45	1	48		
						2	19	592	127
			V6 (WEEK 52)	2010-08-03	10:57	1	48		
						2	24	493	128
			V7 (WEEK 56)	2010-08-31	11:39	1	48		
						2	23	470	105
			SCREENING	2009-11-18	11:19	1	48		
						2	24	487	68
			V1 (WEEK 0)	2009-12-09	11:15	1	48		
						2	24	486	55
			V3 (WEEK 12)	2010-03-03	10:21	1	49		
						2	24	489	84
			V4 (WEEK 24)	2010-05-25	10:20	1	48		
						2	24	434	37
			V5 (WEEK 36)	2010-08-24	12:28	1	48		
						2	24	503	95

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	019	5	V6 (WEEK 52)	2010-12-07	11:26	1	48		
						2	24	487	68
			V7 (WEEK 56)	2011-01-11	11:12	1	49		
						2	24	489	84
	023	4	SCREENING	2010-07-01	14:18	1	48		
						2	24	496	108
			V1 (WEEK 0)	2010-07-20	11:05	1	48		
						2	24	519	111
			V3 (WEEK 12)	2010-10-13	11:53	1	49		
						2	24	511	96
			V4 (WEEK 24)	2011-01-12	12:16	1	48		
						2	24	592	200
			V5 (WEEK 36)	2011-03-21	11:18	1	48		
						2	0		
			V6 (WEEK 52)	2011-07-18	11:59	1	48		
						2	23	642	180
			V7 (WEEK 56)	2011-08-11	12:30	1	48		
						2	20	577	138
	027	20	SCREENING	2010-09-30	14:22	1	48		
						2	24	521	142
			V1 (WEEK 0)	2010-10-21	10:47	1	48		
						2	24	432	66
			V3 (WEEK 12)	2011-01-20	12:00	1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	027	20	V3 (WEEK 12)	2011-01-20	12:00	2	24	467	98
			V4 (WEEK 24)	2011-04-12	12:34	1	48		
						2	24	408	82
			V5 (WEEK 36)	2011-07-06		1	49		
						2	23	463	149
			V6 (WEEK 52)	2011-10-25	9:04	1	48		
						2	24	416	70
			V7 (WEEK 56)	2011-12-01	11:04	1	48		
						2	24	434	84
	030	8	SCREENING	2010-03-18	11:25	1	48		
						2	24	445	105
			V1 (WEEK 0)	2010-03-25	11:07	1	48		
						2	24	439	154
			V3 (WEEK 12)	2010-06-17	11:23	1	48		
						2	24	519	127
			V4 (WEEK 24)	2010-09-03	11:44	1	48		
						2	24	705	115
			V5 (WEEK 36)	2010-12-02	11:26	1	48		
						2	24	620	125
			V6 (WEEK 52)	2011-03-14	11:05	1	48		
						2	24	564	177
			V7 (WEEK 56)	2011-04-11	11:12	1	48		
						2	24	576	105

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	032	8	SCREENING	2010-11-08	10:44	1	49		
						2	24	444	44
			V1 (WEEK 0)	2010-11-18	10:44	1	48		
						2	24	500	65
	033	9	SCREENING	2009-10-28	10:21	1	48		
						2	24	591	105
			V1 (WEEK 0)	2009-11-04	10:24	1	48		
						2	24	644	85
			V3 (WEEK 12)	2010-01-20	10:34	1	75		
						2	3	855	38
			V4 (WEEK 24)	2010-04-21	13:24	1	48		
						2	24	555	85
			V5 (WEEK 36)	2010-07-22	9:31	1	48		
						2	24	640	97
			V6 (WEEK 52)	2010-11-10	10:25	1	74		
						2	54	719	142
			V7 (WEEK 56)	2010-12-06	10:06	1	74		
						2	56	699	112
	042	12	SCREENING	2009-12-16	14:49	1			
						2			
			V1 (WEEK 0)	2010-01-14	13:44	1			
						2			
			V3 (WEEK 12)	2010-05-19	13:06	1			

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	042	12	V3 (WEEK 12)	2010-05-19	13:06	2			
			V4 (WEEK 24)	2010-06-30	11:38	1	61		
						2	20	832	491
			V5 (WEEK 36)	2010-09-22	9:52	1	56		
						2	22	792	419
			V6 (WEEK 52)	2011-01-12	9:15	1	50		
						2	18	594	182
			V7 (WEEK 56)	2011-02-08	9:39	1			
						2			
	043	12	SCREENING	2009-10-21	12:22	1	48		
						2	23	523	54
			V1 (WEEK 0)	2009-11-18	11:14	1	48		
						2	23	523	54
			V3 (WEEK 12)	2010-02-10	12:34	1			
						2			
			V4 (WEEK 24)	2010-05-12	11:36	1			
						2			
	046	11	SCREENING	2009-12-14	14:37	1	79		
						2	52	682	310
			V3 (WEEK 12)	2010-04-07	10:40	1	50		
						2	24	514	107
			V4 (WEEK 24)	2010-07-07	10:41	1	49		
						2	23	551	186

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	046	11	V5 (WEEK 36)	2010-09-22	12:51	1	74		
						2	56	525	122
			V6 (WEEK 52)	2011-01-12	9:46	1	75		
						2	56	529	101
			V7 (WEEK 56)	2011-02-07	12:06	1	74		
						2	56	624	152
	048	11	SCREENING	2010-11-17	12:51	1	74		
						2	56	498	55
			V1 (WEEK 0)	2010-11-22	15:01	1	48		
						2	24	430	36
			V3 (WEEK 12)	2011-02-15	12:25	1	48		
						2	24	454	43
			V4 (WEEK 24)	2011-05-16	13:27	1	74		
						2	56	484	56
			V5 (WEEK 36)	2011-07-26	13:12	1	74		
						2	56	510	60
			V6 (WEEK 52)	2011-11-16	15:30	1	48		
						2	24	491	48
	050	21	V7 (WEEK 56)	2011-12-21	13:46	1	74		
						2	56	516	87
			SCREENING	2010-09-06	13:35	1	50		
						2	22	750	299
			V1 (WEEK 0)	2010-10-27	13:04	1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	050	21	V1 (WEEK 0)	2010-10-27	13:04	2	24	572	85
			V3 (WEEK 12)	2011-01-17	13:16	1	48		
						2	22	594	160
			V4 (WEEK 24)	2011-04-11	12:37	1	48		
						2	24	589	180
			V5 (WEEK 36)	2011-07-04	12:50	1	49		
						2	22	616	154
	052	21	V6 (WEEK 52)	2011-10-24	10:14	1	48		
						2	23	646	149
			V7 (WEEK 56)	2011-11-21	9:38	1	48		
						2	24	573	119
			SCREENING	2010-09-06	17:48	1	48		
						2	24	473	129
			V1 (WEEK 0)	2010-10-28	11:04	1	48		
						2	24	443	92
			V3 (WEEK 12)	2011-01-17	9:10	1	51		
						2	23	445	145
			V4 (WEEK 24)	2011-04-11	9:18	1	50		
						2	21	690	357
			V5 (WEEK 36)	2011-07-04	10:34	1	51		
						2	22	618	317
			V6 (WEEK 52)	2011-10-24	13:37	1	52		
						2	19	562	190
			V7 (WEEK 56)	2011-11-21	11:02	1	50		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	052	21	V7 (WEEK 56)	2011-11-21	11:02	2	23	641	170
	055	5	SCREENING	2010-03-08	10:59	1			
			V1 (WEEK 0)	2010-03-29	11:39	1	51		
						2	24	468	85
	066	16	SCREENING	2010-08-09	13:22	1	48		
			V1 (WEEK 0)	2010-09-13	9:43	2	23	656	142
						1	48		
						2	24	636	123
	067	16	SCREENING	2010-11-02	11:42	1	48		
			V1 (WEEK 0)	2010-11-18	11:14	2	24	389	62
						1	48		
						2	24	401	55
	071	18	SCREENING	2010-10-20	0:34	1	49		
			V1 (WEEK 0)	2010-11-09	2:58	2	23	792	230
						1	49		
			V3 (WEEK 12)	2011-02-03	1:40	2	24	514	77
						1	49		
			V4 (WEEK 24)	2011-05-04	10:45	2	23	703	106
						1	48		
						2	24	638	269

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	071	18	V5 (WEEK 36)	2011-07-19	10:46	1	49		
						2	24	577	108
			V6 (WEEK 52)	2011-11-17	12:35	1	55		
						2	20	582	215
			V7 (WEEK 56)	2011-12-05	13:04	1	48		
						2	20	442	104
	080	13	SCREENING	2010-11-15	10:05	1	48		
						2	23	544	47
			V1 (WEEK 0)	2010-11-18	10:41	1	48		
						2	24	504	83
			V3 (WEEK 12)	2011-02-09	10:09	1	48		
						2	24	460	63
	081	17	SCREENING	2010-10-04	13:29	1	48		
						2	18	558	166
			V1 (WEEK 0)	2010-10-14	21:55	1	50		
						2	18	697	189
			V3 (WEEK 12)	2011-01-10	9:17	1	48		
						2	18	513	183
			V4 (WEEK 24)	2011-04-06	12:49	1	50		
						2	12	559	131
			V5 (WEEK 36)	2011-06-20		1	48		
						2	19	651	174
			V6 (WEEK 52)	2011-10-24		1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	081	17	V6 (WEEK 52)	2011-10-24		2	16	559	333
			V7 (WEEK 56)	2011-11-22		1	48		
						2	14	722	203
	083	17	SCREENING	2010-10-26	21:23	1	49		
						2	17	739	334
			V1 (WEEK 0)	2010-11-10	10:11	1	48		
						2	14	452	116
			V3 (WEEK 12)	2011-02-02	13:27	1	48		
						2	18	571	201
			V4 (WEEK 24)	2011-04-26	14:15	1	49		
						2	20	613	184
			V5 (WEEK 36)	2010-07-25		1	49		
						2	22	653	182
			V6 (WEEK 52)	2011-11-09		1	48		
						2	22	673	169
			V7 (WEEK 56)	2011-12-06		1	49		
						2	17	765	320
	087	16	SCREENING	2010-11-09	10:39	1	48		
						2	24	522	103
			V1 (WEEK 0)	2010-11-29	9:04	1	48		
						2	24	491	78
			V3 (WEEK 12)	2011-02-17	11:08	1	48		
						2	24	624	103

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	087	16	V4 (WEEK 24)	2011-03-07	10:51	1	48		
						2	24	572	87
			V5 (WEEK 36)	2011-08-10	12:33	1	48		
						2	24	565	123
			V6 (WEEK 52)	2011-11-28	12:00	1	48		
						2	24	604	104
	089	5	V7 (WEEK 56)	2011-12-28	11:06	1	48		
						2	23	707	137
			V1 (WEEK 0)	2010-11-16	11:11	1			
						2			
			V3 (WEEK 12)	2011-02-07	11:20	1	55		
						2	17	1076	351
	093	17	SCREENING	2010-11-29	9:05	1	49		
						2	21	700	226
			V1 (WEEK 0)	2010-12-02	12:35	1	48		
						2	17	663	314
			V3 (WEEK 12)	2011-02-25	15:09	1	55		
						2	21	634	228
			V4 (WEEK 24)	2011-05-23	14:54	1	55		
						2	23	590	355
			V5 (WEEK 36)	2011-08-16		1	48		
						2	12	820	278
			V6 (WEEK 52)	2011-12-06		1	54		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	093	17	V6 (WEEK 52)	2011-12-06		2	10	982	715
			V7 (WEEK 56)	2011-12-28		1	48		
						2	15	641	315
	097	12	SCREENING	2010-10-27	12:10	1	55		
						2	21	614	322
			V1 (WEEK 0)	2010-11-17	9:29	1	50		
						2	24	607	356
			V3 (WEEK 12)	2011-02-09	9:47	1	56		
						2	22	896	457
	001	1	SCREENING	2009-04-02	9:48	1	48		
						2	21	662	205
			V1 (WEEK 0)	2009-04-09	9:25	1	48		
						2	19	705	213
			V3 (WEEK 12)	2009-07-07	10:05	1	49		
						2	23	616	175
			V4 (WEEK 24)	2009-09-17	10:09	1	50		
						2	21	551	104
Placebo	005	2	V5 (WEEK 36)	2009-12-10	11:40	1	48		
						2	22	685	236
			SCREENING	2009-05-19	15:41	1	74		
						2	56	506	73
			V1 (WEEK 0)	2009-06-04	10:12	1	74		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	005	2	V1 (WEEK 0)	2009-06-04	10:12	2	55	498	117
			V3 (WEEK 12)	2009-08-25	10:03	1	74		
						2	56	470	72
			V4 (WEEK 24)	2009-11-18	11:59	1	74		
						2	56	477	91
			V5 (WEEK 36)	2010-02-16	11:51	1	74		
						2	52	481	90
			V6 (WEEK 52)	2010-06-02	12:06	1	83		
						2	52	476	78
	009	1	V7 (WEEK 56)	2010-07-08	9:51	1	74		
						2	56	499	63
			SCREENING	2009-08-06	12:24	1	48		
						2	14	559	161
			V1 (WEEK 0)	2009-09-08	10:07	1	49		
						2	21	675	157
			V3 (WEEK 12)	2009-12-10	10:41	1	48		
						2	24	596	114
			V4 (WEEK 24)	2010-03-04	11:51	1	48		
						2	24	422	135
			V5 (WEEK 36)	2010-05-11	9:36	1	48		
						2	23	543	54
			V6 (WEEK 52)	2010-09-03	12:21	1	48		
						2	24	480	133

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	011	1	SCREENING	2009-11-05	14:30	1	48		
						2	24	475	75
			V1 (WEEK 0)	2009-11-26	9:52	1	48		
						2	24	478	72
			V3 (WEEK 12)	2010-02-18	10:06	1	48		
						2	24	465	57
			V4 (WEEK 24)	2010-05-06	13:06	1	48		
						2	24	450	72
			V5 (WEEK 36)	2010-08-05	15:30	1	48		
						2	24	557	229
	013	4	SCREENING	2009-08-17	11:33	1	48		
						2	24	517	76
			V1 (WEEK 0)	2009-09-16	10:54	1	48		
						2	24	476	70
			V3 (WEEK 12)	2009-12-09	11:01	1	48		
						2	24	474	64
			V4 (WEEK 24)	2010-03-04	11:07	1	48		
						2	24	422	48
			V5 (WEEK 36)	2010-05-20	11:24	1	48		
						2	24	436	87
			V6 (WEEK 52)	2010-09-16	12:27	1	48		
						2	24	491	64
			V7 (WEEK 56)	2010-10-20	12:36	1	48		
						2	24	428	70

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	016	4	SCREENING	2010-02-01	11:31	1	48		
						2	24	362	45
			V1 (WEEK 0)	2010-03-01	10:52	1	48		
						2	24	368	57
			V3 (WEEK 12)	2010-05-19	10:15	1	48		
						2	24	340	42
			V4 (WEEK 24)	2010-08-09	11:34	1	48		
						2	24	354	44
			V5 (WEEK 36)	2010-11-08	10:58	1	48		
						2	24	359	64
			V6 (WEEK 52)	2011-02-28	11:54	1	48		
						2	24	412	76
			V7 (WEEK 56)	2011-04-07	12:43	1	48		
						2	24	402	63
	018	5	SCREENING	2009-11-03	12:53	1			
						2			
			V1 (WEEK 0)	2009-11-23	12:23	1	48		
						2	24	465	96
			V3 (WEEK 12)	2010-02-16	11:39	1	53		
						2	24	555	134
			V4 (WEEK 24)	2010-05-11	11:50	1	48		
						2	24	511	110
			V5 (WEEK 36)	2010-07-27	10:19	1	53		
						2	24	555	134

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	018	5	V6 (WEEK 52)	2010-11-23	12:03	1	48	511	110
						2	24		
			V7 (WEEK 56)	2010-12-14	10:59	1			
						2			
	020	5	SCREENING	2010-01-27	17:28	1			
						2			
			V1 (WEEK 0)	2010-02-22	12:52	1			
						2			
	024	4	SCREENING	2010-07-16	11:38	1	48	453	86
						2	24		
			V1 (WEEK 0)	2010-08-16	10:49	1	48		
						2	24		
			V3 (WEEK 12)	2010-11-10	12:25	1	48		
						2	24		
			V4 (WEEK 24)	2011-02-02	11:17	1	48		
						2	24		
			V5 (WEEK 36)	2011-04-18	11:07	1	48		
						2	24		
			V6 (WEEK 52)	2011-08-08	11:54	1	48		
						2	24		
	028	20	SCREENING	2010-11-18	11:44	1	48	466	52
						2	24		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	028	20	V1 (WEEK 0)	2010-11-26	10:14	1	48		
						2	24	382	32
			V3 (WEEK 12)	2011-02-22		1	48		
						2	24	415	92
			V4 (WEEK 24)	2011-05-24	11:55	1	48		
						2	24	438	77
			V5 (WEEK 36)	2011-08-25	14:40	1	48		
						2	24	373	57
	029	8	V6 (WEEK 52)	2011-11-24	9:33	1	48		
						2	24	534	291
			V7 (WEEK 56)	2011-12-20	9:38	1	48		
						2	22	564	120
			SCREENING	2010-01-26	11:05	1	48		
						2	24	492	68
			V1 (WEEK 0)	2010-01-29	11:26	1	48		
						2	24	543	79
			V3 (WEEK 12)	2010-04-20	10:29	1	48		
						2	24	421	67
			V4 (WEEK 24)	2010-07-05	10:30	1	48		
						2	24	498	50
			V5 (WEEK 36)	2010-09-30	10:49	1	48		
						2	24	478	50
			V6 (WEEK 52)	2011-02-01	10:43	1	48		
						2	24	521	75

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	029	8	V7 (WEEK 56)	2011-02-23	10:54	1	48		
						2	23	511	75
	031	8	SCREENING	2010-05-06	12:50	1	48		
						2	24	447	68
			V1 (WEEK 0)	2010-05-20	10:47	1	48		
						2	24	410	73
			V3 (WEEK 12)	2010-08-17	11:23	1	48		
						2	24	377	46
			V4 (WEEK 24)	2010-11-09	10:09	1	48		
						2	24	382	50
			V5 (WEEK 36)	2011-01-25	10:39	1	48		
						2	24	367	45
			V6 (WEEK 52)	2011-05-17	12:48	1	48		
						2	24	373	45
			V7 (WEEK 56)	2011-06-14	11:08	1	48		
						2	24	378	64
	041	12	SCREENING	2009-09-23	12:15	1	50		
						2	24	430	47
			V1 (WEEK 0)	2009-10-09	11:52	1	49		
						2	24	434	79
			V3 (WEEK 12)	2010-01-05	14:31	1			
						2			
			V4 (WEEK 24)	2010-03-24	12:11	1			

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	041	12	V4 (WEEK 24)	2010-03-24	12:11	2			
			V5 (WEEK 36)	2010-06-16	10:28	1	48		
						2	24	407	55
			V6 (WEEK 52)	2010-10-06	10:48	1			
						2			
			V7 (WEEK 56)	2010-11-03	9:22	1	48		
						2	24	396	40
	044	12	SCREENING	2009-11-04	11:45	1			
						2			
			V1 (WEEK 0)	2009-12-02	11:21	1			
						2			
			V3 (WEEK 12)	2010-02-24	12:08	1			
						2			
			V4 (WEEK 24)	2010-05-26	10:13	1			
						2			
			V5 (WEEK 36)	2010-08-18	12:23	1	48		
						2	24	582	96
			V6 (WEEK 52)	2010-12-01	10:08	1	49		
						2	23	569	76
	045	11	V7 (WEEK 56)	2011-01-05	11:58	1			
						2			
			SCREENING	2009-12-07	14:48	1	48		
						2	24	427	40

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	045	11	V1 (WEEK 0)	2009-12-21	13:32	1	74		
						2	56	421	91
			V3 (WEEK 12)	2010-03-15	11:00	1	74		
						2	56	381	79
			V4 (WEEK 24)	2010-06-07	12:10	1	74		
						2	56	395	71
			V5 (WEEK 36)	2010-09-06	12:31	1	74		
						2	56	372	51
	047	11	V6 (WEEK 52)	2010-12-15	12:00	1	48		
						2	22	637	167
			V7 (WEEK 56)	2011-01-17	12:12	1	78		
						2	56	475	133
			SCREENING	2010-07-12	11:56	1	48		
						2	24	427	60
			V1 (WEEK 0)	2010-08-02	13:17	1	74		
						2	56	412	65
			V3 (WEEK 12)	2010-10-20	14:39	1	74		
						2	56	469	76
			V4 (WEEK 24)	2011-01-10	12:13	1	77		
						2	56	453	67
			V5 (WEEK 36)	2011-04-12	12:16	1	74		
						2	56	449	36
			V6 (WEEK 52)	2011-07-27	12:11	1	74		
						2	56	452	46

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	047	11	V7 (WEEK 56)	2011-08-29	9:58	1	74		
						2	56	467	60
	049	21	SCREENING	2010-09-06	9:48	1	48		
						2	24	512	56
			V1 (WEEK 0)	2010-10-27	10:24	1	48		
						2	24	512	56
			V3 (WEEK 12)	2011-01-18	9:30	1	48		
						2	24	526	66
			V4 (WEEK 24)	2011-04-12	9:27	1	48		
						2	22	663	340
			V5 (WEEK 36)	2011-07-05	14:25	1	48		
						2	24	463	82
	051	21	SCREENING	2010-09-06	11:41	1	74		
						2	56	527	81
			V1 (WEEK 0)	2010-10-28	13:23	1	48		
						2	24	440	51
			V3 (WEEK 12)	2011-02-01	8:55	1	48		
						2	24	426	47
			V4 (WEEK 24)	2011-04-12	14:33	1	49		
						2	19	526	250
			V5 (WEEK 36)	2011-07-05	15:40	1	48		
						2	24	483	61
			V6 (WEEK 52)	2011-10-25	10:09	1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	051	21	V6 (WEEK 52)	2011-10-25	10:09	2	24	467	83
			V7 (WEEK 56)	2011-11-22	9:12	1	48		
						2	24	463	40
	056	5	SCREENING	2010-03-31	12:01	1	48		
						2	23	560	120
			V1 (WEEK 0)	2010-04-21	10:42	1	48		
						2	23	560	120
			V4 (WEEK 24)	2010-10-05	11:29	1			
						2			
			V5 (WEEK 36)	2011-01-04	10:58	1			
						2			
			V6 (WEEK 52)	2011-04-19	10:49	1	48		
						2	24	462	71
			V7 (WEEK 56)	2011-05-18	12:07	1	48		
						2	24	495	45
	065	16	SCREENING	2010-08-10	12:58	1	49		
						2	24	466	78
			V3 (WEEK 12)	2010-11-22	10:09	1	48		
						2	22	494	129
			V4 (WEEK 24)	2011-01-17	12:29	1	48		
	068	16				2	23	440	115
			SCREENING	2010-10-26	10:47	1	61		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	068	16	SCREENING	2010-10-26	10:47	2	23	551	113
			V1 (WEEK 0)	2010-11-22	11:29	1	49		
						2	24	511	75
			V3 (WEEK 12)	2011-02-10	10:36	1	49		
						2	24	512	73
			V4 (WEEK 24)	2011-05-03	11:35	1	48		
						2	24	582	108
			V5 (WEEK 36)	2011-08-10	9:55	1	52		
	069	23				2	23	589	112
			V6 (WEEK 52)	2011-11-28	13:17	1	48		
						2	24	643	108
			SCREENING	2010-11-24	10:59	1	48		
						2	24	490	175
			V1 (WEEK 0)	2010-12-07	13:43	1	48		
						2	23	455	118
			V3 (WEEK 12)	2011-03-09	11:27	1	48		
						2	24	451	147
			V4 (WEEK 24)	2011-05-19	10:50	1	52		
						2	24	451	107
			V5 (WEEK 36)	2011-08-24	11:04	1	48		
						2	24	412	58
			V6 (WEEK 52)	2011-12-14	11:06	1	48		
						2	17	509	166
			V7 (WEEK 56)	2012-01-11	11:10	1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	069	23	V7 (WEEK 56)	2012-01-11	11:10	2	23	437	107
			SCREENING	2010-12-01	0:40	1	48		
	072	18	V1 (WEEK 0)	2010-12-21	0:36	2	24	587	171
						1	49		
			V3 (WEEK 12)	2011-03-15	10:04	2	24	610	117
						1	48		
			V4 (WEEK 24)	2011-06-07	10:57	2	21	430	126
						1	48		
			V5 (WEEK 36)	2011-09-08	11:34	2	23	546	88
						1	49		
			V6 (WEEK 52)	2011-12-15	10:47	2	24	757	153
						1	48		
			V7 (WEEK 56)	2012-01-17	12:47	2	24	655	154
						1	48		
	079	13	SCREENING	2010-07-19	13:54	2	23	640	219
						1	48		
			V1 (WEEK 0)	2010-08-06	12:26	2	24	635	225
						1	48		
			V3 (WEEK 12)	2010-11-16	13:22	2	23	559	119
						1	48		
			V4 (WEEK 24)	2011-01-27	12:44	2	24	698	198
						1	48		
						2	24	639	212

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	079	13	V5 (WEEK 36)	2011-04-11	13:55	1	48		
						2	24	560	138
			V6 (WEEK 52)	2011-06-21	14:19	1	48		
						2	23	623	148
			V7 (WEEK 56)	2011-07-19	13:12	1	48		
						2	11	715	229
	082	17	SCREENING	2010-10-06	21:01	1			
						2			
			V1 (WEEK 0)	2010-10-14	9:29	1	48		
						2	15	570	208
			V3 (WEEK 12)	2011-01-05	13:00	1	49		
						2	23	589	148
			V4 (WEEK 24)	2011-04-06	13:10	1	48		
						2	23	430	92
			V5 (WEEK 36)	2011-06-22		1	48		
						2	19	671	199
			V6 (WEEK 52)	2011-10-12		1	48		
						2	19	662	299
			V7 (WEEK 56)	2011-11-24		1	48		
						2	17	694	187
	084	17	SCREENING	2010-11-08	21:40	1	49		
						2	19	925	449
			V1 (WEEK 0)	2010-04-21	12:18	1	49		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	084	17	V1 (WEEK 0)	2010-04-21	12:18	2	19	774	285
			V3 (WEEK 12)	2011-02-08	14:31	1	42		
						2	19	921	583
			V4 (WEEK 24)	2011-05-10	14:36	1	48		
						2	20	588	184
			V5 (WEEK 36)	2011-08-02		1	49		
						2	14	739	364
			V6 (WEEK 52)	2011-11-22		1	53		
						2	14	832	471
			V7 (WEEK 56)	2011-12-15		1	48		
						2	16	684	190
	086	21	SCREENING	2010-10-04	9:36	1	48		
						2	24	639	249
			V1 (WEEK 0)	2010-10-28	15:35	1	48		
						2	24	465	38
			V3 (WEEK 12)	2011-01-18	12:48	1	48		
						2	24	422	57
			V4 (WEEK 24)	2011-04-12	13:01	1	48		
						2	21	454	72
			V5 (WEEK 36)	2011-07-05	13:14	1	48		
						2	24	439	48
			V6 (WEEK 52)	2011-10-25	12:36	1	48		
						2	23	472	77
			V7 (WEEK 56)	2011-11-22	11:22	1	48		

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Listing 16.2.6.6: Choice Reaction Time - GNG (CRTGNG) (Go/NoGo)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	086	21	V7 (WEEK 56)	2011-11-22	11:22	2	24	394	58
	088	16	SCREENING	2010-11-30	11:23	1	48	514	114
						2	24		
						1	48		
						2	24		
						1	48		
						2	24		
						1	48		
						2	15	617	200

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	002	1	SCREENING	2009-04-16	11:57	1	40		
						2	20	568	156
			V1 (WEEK 0)	2009-04-23	9:57	1	40		
						2	20	772	167
			V3 (WEEK 12)	2009-07-16	9:53	1	40		
						2	20	567	112
			V4 (WEEK 24)	2009-10-08	10:09	1	40		
						2	20	652	185
			V5 (WEEK 36)	2010-01-05	11:04	1	42		
						2	18	1110	563
			V6 (WEEK 52)	2010-04-22	9:47	1	40		
						2	20	714	163
			V7 (WEEK 56)	2010-05-20	10:24	1	40		
						2	20	897	272
	004	1	SCREENING	2009-06-22	8:46	1	40		
						2	18	840	299
			V1 (WEEK 0)	2009-07-16	11:10	1	40		
						2	19	1085	304
	006	2	SCREENING	2010-01-25	10:53	1	40		
						2	20	723	112
			V3 (WEEK 12)	2010-05-21	11:48	1	42		
						2	18	964	308
			V4 (WEEK 24)	2010-08-13	12:57	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	006	2	V4 (WEEK 24)	2010-08-13	12:57	2	20	935	159
			V5 (WEEK 36)	2010-11-04	10:33	1	40		
						2	20	1302	386
			V6 (WEEK 52)	2011-02-24	12:04	1	40		
						2	20	718	116
			V7 (WEEK 56)	2011-03-22	10:48	1	40		
						2	20	1156	141
	010	1	SCREENING	2009-06-25	11:42	1	40		
						2	20	915	273
			V1 (WEEK 0)	2009-07-21	11:26	1	40		
						2	20	997	255
	012	1	V3 (WEEK 12)	2009-10-13	10:15	1	40		
						2	20	1118	344
			SCREENING	2010-06-17	13:46	1	40		
						2	19	893	362
	014	4	V1 (WEEK 0)	2010-07-19	10:44	1	40		
						2	20	899	301
			SCREENING	2009-10-07	13:02	1	40		
						2	20	829	176
			V1 (WEEK 0)	2009-11-02	11:17	1	40		
						2	20	684	149
			V3 (WEEK 12)	2010-01-25	10:43	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	014	4	V3 (WEEK 12)	2010-01-25	10:43	2	20	663	160
			V4 (WEEK 24)	2010-04-22	12:11	1	40		
						2	20	637	146
			V5 (WEEK 36)	2010-07-15	11:31	1	40		
						2	20	697	124
			V6 (WEEK 52)	2010-10-28	13:35	1	40		
						2	20	627	166
			V7 (WEEK 56)	2010-12-02	12:39	1	40		
						2	20	545	59
	015	4	SCREENING	2010-01-21	12:14	1	40		
						2	1	1687	
			V1 (WEEK 0)	2010-02-22	10:52	1	40		
						2	20	762	95
			V3 (WEEK 12)	2010-05-17	11:04	1	41		
						2	15	1592	506
			V4 (WEEK 24)	2010-08-02	10:53	1	41		
						2	17	1178	443
			V5 (WEEK 36)	2010-10-27	11:12	1	41		
						2	19	772	136
			V6 (WEEK 52)	2011-02-21	13:38	1	40		
						2	20	732	138
			V7 (WEEK 56)	2011-03-22	11:23	1	40		
						2	20	753	147

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	017	5	SCREENING	2009-07-14	11:32	1	41		
						2	20	721	195
			V1 (WEEK 0)	2009-08-05	10:17	1	40		
						2	20	715	139
			V3 (WEEK 12)	2009-10-28	13:00	1	41		
						2	19	593	95
			V4 (WEEK 24)	2010-01-20	11:43	1	40		
						2	20	851	334
	019	5	V5 (WEEK 36)	2010-04-13	11:50	1	40		
						2	19	958	471
			V6 (WEEK 52)	2010-08-03	11:02	1	40		
						2	20	979	375
			V7 (WEEK 56)	2010-08-31	11:46	1	40		
						2	20	900	222
			SCREENING	2009-11-18	11:24	1	40		
						2	20	745	117
			V1 (WEEK 0)	2009-12-09	11:19	1	41		
						2	18	859	170
			V3 (WEEK 12)	2010-03-03	10:26	1	40		
						2	20	1026	268
			V4 (WEEK 24)	2010-05-25	10:28	1	40		
						2	20	918	212
			V5 (WEEK 36)	2010-08-24	12:33	1	40		
						2	20	823	165

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	019	5	V6 (WEEK 52)	2010-12-07	11:32	1	40		
						2	20	1050	292
			V7 (WEEK 56)	2011-01-11	11:17	1	40		
						2	20	829	133
	023	4	SCREENING	2010-07-01	14:21	1	40		
						2	20	892	158
			V1 (WEEK 0)	2010-07-20	11:09	1	40		
						2	20	830	107
			V3 (WEEK 12)	2010-10-13	11:57	1	40		
						2	20	1057	223
			V4 (WEEK 24)	2011-01-12	12:20	1	40		
						2	20	714	121
			V5 (WEEK 36)	2011-03-21	11:22	1	42		
						2	16	1187	496
			V6 (WEEK 52)	2011-07-18	12:03	1	40		
						2	17	1175	414
			V7 (WEEK 56)	2011-08-11	12:34	1	42		
						2	19	1123	287
	027	20	SCREENING	2010-09-30	14:26	1	40		
						2	20	879	350
			V1 (WEEK 0)	2010-10-21	10:51	1	40		
						2	20	701	157
			V3 (WEEK 12)	2011-01-20	12:03	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	027	20	V3 (WEEK 12)	2011-01-20	12:03	2	20	706	126
			V4 (WEEK 24)	2011-04-12		1	40		
						2	20	595	128
			V5 (WEEK 36)	2011-07-06	11:02	1	40		
						2	20	663	124
			V6 (WEEK 52)	2011-10-25	9:08	1	40		
						2	20	483	109
			V7 (WEEK 56)	2011-12-01	11:07	1	40		
						2	20	677	92
	030	8	SCREENING	2010-03-18	11:30	1	44		
						2	15	1464	541
			V1 (WEEK 0)	2010-03-25	11:11	1	40		
						2	19	1026	272
			V3 (WEEK 12)	2010-06-17	11:27	1	40		
						2	20	687	102
			V4 (WEEK 24)	2010-09-03	11:47	1	40		
						2	20	898	214
			V5 (WEEK 36)	2010-12-02	11:30	1	40		
						2	20	854	152
			V6 (WEEK 52)	2011-03-14	11:10	1	41		
						2	14	1107	351
			V7 (WEEK 56)	2011-04-11	11:16	1	40		
						2	18	880	190

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	032	8	SCREENING	2010-11-08	10:48	1	40		
						2	20	1243	337
			V1 (WEEK 0)	2010-11-18	10:48	1	40		
						2	19	1382	429
	033	9	SCREENING	2009-10-28	10:25	1	40		
						2	20	1133	246
			V1 (WEEK 0)	2009-11-04	10:27	1	40		
						2	20	961	225
			V3 (WEEK 12)	2010-01-20	10:38	1	40		
						2	1	1054	
			V4 (WEEK 24)	2010-04-21	13:28	1	40		
						2	20	871	233
			V5 (WEEK 36)	2010-07-22	9:35	1	40		
						2	19	1074	299
			V6 (WEEK 52)	2010-11-10	10:29	1	41		
						2	19	959	199
			V7 (WEEK 56)	2010-12-06	10:09	1	40		
						2	20	971	277
	042	12	SCREENING	2009-12-16	14:55	1			
						2			
			V1 (WEEK 0)	2010-01-14	13:52	1	48		
						2	18	1126	556
			V3 (WEEK 12)	2010-05-19	13:11	1			

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	042	12	V3 (WEEK 12)	2010-05-19	13:11	2			
			V4 (WEEK 24)	2010-06-30	11:43	1	49		
						2	17	1187	491
			V5 (WEEK 36)	2010-09-22	9:56	1	45		
						2	19	1244	342
			V6 (WEEK 52)	2011-01-12	9:19	1	44		
						2	20	773	395
			V7 (WEEK 56)	2011-02-08	9:43	1	45		
						2	19	1088	456
	043	12	SCREENING	2009-10-21	12:27	1	41		
						2	16	1073	421
			V1 (WEEK 0)	2009-11-18	11:18	1	42		
						2	17	1458	523
			V3 (WEEK 12)	2010-02-10	12:40	1			
						2			
	046	11	V4 (WEEK 24)	2010-05-12	11:40	1			
						2			
			SCREENING	2009-12-14	14:42	1	47		
						2	11	1461	522
			V1 (WEEK 0)	2010-01-11	15:23	1	43		
						2	11	1746	389
			V3 (WEEK 12)	2010-04-07	10:46	1	45		
						2	17	1025	381

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	046	11	V4 (WEEK 24)	2010-07-07	10:47	1	46		
						2	10	1506	667
			V5 (WEEK 36)	2010-09-22	12:57	1	41		
						2	19	1375	533
			V6 (WEEK 52)	2011-01-12	9:51	1	41		
						2	18	1423	531
			V7 (WEEK 56)	2011-02-07	12:12	1	48		
						2	10	1436	649
	048	11	SCREENING	2010-11-17	12:55	1	40		
						2	20	824	122
			V1 (WEEK 0)	2010-11-22	15:07	1	40		
						2	20	681	84
			V3 (WEEK 12)	2011-02-15	12:29	1	40		
						2	20	679	137
			V4 (WEEK 24)	2011-05-16	13:31	1	40		
						2	20	861	230
			V5 (WEEK 36)	2011-07-26	13:17	1	40		
						2	20	674	213
			V6 (WEEK 52)	2011-11-16	15:36	1	40		
						2	20	692	121
			V7 (WEEK 56)	2011-12-21	13:51	1	45		
						2	20	782	130
	050	21	SCREENING	2010-09-06	13:40	1	41		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	050	21	SCREENING	2010-09-06	13:40	2	20	1297	375
			V1 (WEEK 0)	2010-10-27	13:07	1	41		
						2	18	981	365
			V3 (WEEK 12)	2011-01-17	13:20	1	40		
						2	20	1078	312
			V4 (WEEK 24)	2011-04-11	12:41	1	40		
						2	19	1347	336
			V5 (WEEK 36)	2011-07-04	12:54	1	41		
						2	19	1396	420
	052	21	V6 (WEEK 52)	2011-10-24	10:19	1	46		
						2	18	1229	463
			V7 (WEEK 56)	2011-11-21	9:42	1	40		
						2	20	1070	262
			SCREENING	2010-09-06	17:55	1	49		
						2	12	1466	584
			V1 (WEEK 0)	2010-10-28	11:09	1	47		
						2	16	1126	316
			V3 (WEEK 12)	2011-01-17	9:16	1	48		
						2	13	1333	591
			V4 (WEEK 24)	2011-04-11	9:23	1	43		
						2	20	1132	494
			V5 (WEEK 36)	2011-07-04	10:38	1	42		
						2	16	1192	446
			V6 (WEEK 52)	2011-10-24	13:42	1	48		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	052	21	V6 (WEEK 52)	2011-10-24	13:42	2	13	1348	622
			V7 (WEEK 56)	2011-11-21	11:06	1	42		
						2	19	966	302
	055	5	SCREENING	2010-03-08	11:04	1	42		
						2	14	1274	464
			V1 (WEEK 0)	2010-03-29	11:44	1	40		
						2	20	895	386
	066	16	SCREENING	2010-08-09	13:26	1	45		
						2	12	1564	619
			V1 (WEEK 0)	2010-09-13	9:48	1	45		
						2	16	1623	409
			V3 (WEEK 12)	2010-11-30	11:08	1	42		
						2	3	1773	313
	067	16	SCREENING	2010-11-02	11:46	1	40		
						2	20	614	99
			V1 (WEEK 0)	2010-11-18	11:18	1	40		
						2	20	555	83
	071	18	SCREENING	2010-10-20	0:37	1	45		
						2	11	1485	425
			V1 (WEEK 0)	2010-11-09	3:02	1	41		
						2	20	1415	329

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	071	18	V3 (WEEK 12)	2011-02-03	1:44	1	44		
						2	15	1397	406
			V4 (WEEK 24)	2011-05-04	10:49	1	43		
						2	18	1536	219
			V5 (WEEK 36)	2011-07-19	10:50	1	41		
						2	19	1346	266
			V6 (WEEK 52)	2011-11-17	12:44	1	41		
						2	18	762	346
			V7 (WEEK 56)	2011-12-05	13:11	1	49		
						2	16	1316	418
	080	13	SCREENING	2010-11-15	10:09	1	40		
						2	20	1082	312
			V1 (WEEK 0)	2010-11-18	10:44	1	40		
						2	20	885	217
			V3 (WEEK 12)	2011-02-09	10:13	1	40		
						2	20	847	258
	081	17	SCREENING	2010-10-04	13:38	1	42		
						2	18	822	453
			V1 (WEEK 0)	2010-10-14	13:38	1	42		
						2	18	822	453
			V3 (WEEK 12)	2011-01-10	9:21	1	40		
						2	20	740	265
			V4 (WEEK 24)	2011-04-06	12:52	1	42		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	081	17	V4 (WEEK 24)	2011-04-06	12:52	2	15	880	357
			V5 (WEEK 36)	2011-06-20		1	42		
						2	16	1277	572
			V6 (WEEK 52)	2011-10-24		1	42		
						2	14	1461	649
			V7 (WEEK 56)	2011-11-22	6:11	1	41		
						2	12	878	454
	083	17	SCREENING	2010-10-26	21:28	1	42		
						2	13	995	370
			V1 (WEEK 0)	2010-11-10	10:15	1	41		
						2	19	975	548
			V3 (WEEK 12)	2011-02-02	13:30	1	40		
						2	19	736	241
			V4 (WEEK 24)	2011-04-26	14:17	1	40		
						2	19	865	319
			V5 (WEEK 36)	2011-07-25		1	40		
						2	19	1028	474
			V6 (WEEK 52)	2011-11-09		1	40		
						2	16	1300	469
			V7 (WEEK 56)	2011-12-06		1	42		
						2	13	1014	270
	087	16	SCREENING	2010-11-09	10:44	1	40		
						2	19	1011	275

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	087	16	V1 (WEEK 0)	2010-11-29	9:07	1	40		
						2	20	1022	244
			V3 (WEEK 12)	2011-02-17	11:11	1	41		
						2	17	1500	501
			V4 (WEEK 24)	2011-03-07	10:54	1	41		
						2	19	1321	388
			V5 (WEEK 36)	2011-08-10	12:37	1	42		
						2	17	1437	420
	089	5	V6 (WEEK 52)	2011-11-28	12:03	1	45		
						2	11	1609	620
			V7 (WEEK 56)	2011-12-28	11:11	1	42		
						2	20	1417	493
	093	17	V1 (WEEK 0)	2010-11-16	11:16	1	41		
						2	19	1887	241
			SCREENING	2010-05-29	20:08	1	40		
						2	5	514	23
			V1 (WEEK 0)	2010-12-02	12:38	1	44		
						2	13	1302	698
			V3 (WEEK 12)	2011-02-25	14:57	1	44		
						2	14	1251	508
			V4 (WEEK 24)	2011-05-23	15:00	1	45		
						2	12	1052	543
			V5 (WEEK 36)	2011-08-16		1	43		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
ACI-91	093	17	V5 (WEEK 36)	2011-08-16		2	8	1315	724
			V6 (WEEK 52)	2011-12-06		1	42		
						2	9	1001	463
			V7 (WEEK 56)	2011-12-28		1	40		
						2	13	1165	473
	097	12	SCREENING	2010-10-27	12:13	1	40		
						2	20	771	346
			V1 (WEEK 0)	2010-11-17	9:33	1	45		
						2	18	1056	465
			V3 (WEEK 12)	2011-02-09	9:52	1	49		
Placebo	001	1				2	19	683	268
			V3 (WEEK 12)	2009-07-07	10:10	1	48		
						2	14	1469	626
			V4 (WEEK 24)	2009-09-17	10:13	1	44		
						2	13	1474	567
	005	2	V5 (WEEK 36)	2009-12-10	11:43	1	40		
						2	20	1068	436
			SCREENING	2009-05-19	15:48	1	41		
						2	18	980	300
			V1 (WEEK 0)	2009-06-04	10:16	1	41		
						2	19	1015	320
			V3 (WEEK 12)	2009-08-25	10:07	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	005	2	V3 (WEEK 12)	2009-08-25	10:07	2	20	875	211
			V4 (WEEK 24)	2009-11-18	12:04	1	41		
						2	20	871	261
			V5 (WEEK 36)	2010-02-16	11:56	1	41		
						2	20	960	321
			V6 (WEEK 52)	2010-06-02	12:09	1	40		
	009	1				2	20	742	311
			V7 (WEEK 56)	2010-07-08	9:55	1	40		
						2	20	871	309
			SCREENING	2009-08-06	12:27	1	40		
						2	20	771	239
			V1 (WEEK 0)	2009-09-08	10:11	1	46		
						2	8	1612	509
			V3 (WEEK 12)	2009-12-10	10:44	1	41		
						2	19	864	252
			V4 (WEEK 24)	2010-03-04	11:53	1	40		
						2	20	713	207
			V5 (WEEK 36)	2010-05-11	9:40	1	42		
						2	11	1065	464
			V6 (WEEK 52)	2010-09-03	12:23	1	40		
						2	20	606	163
	011	1	SCREENING	2009-11-05	14:34	1	41		
						2	20	1090	429

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	011	1	V1 (WEEK 0)	2009-11-26	9:55	1	40		
						2	20	994	365
			V3 (WEEK 12)	2010-02-18	10:10	1	40		
						2	20	908	251
			V4 (WEEK 24)	2010-05-06	13:10	1	40		
						2	19	1046	346
			V5 (WEEK 36)	2010-08-05	15:32	1	40		
						2	20	954	343
	013	4	SCREENING	2009-08-17	11:38	1	40		
						2	20	781	283
			V1 (WEEK 0)	2009-09-16	10:58	1	40		
						2	20	655	79
			V3 (WEEK 12)	2009-12-09	11:05	1	40		
						2	20	853	192
			V4 (WEEK 24)	2010-03-04	11:11	1	40		
						2	20	635	79
			V5 (WEEK 36)	2010-05-20	11:27	1	40		
						2	20	680	91
			V6 (WEEK 52)	2010-09-16	12:31	1	40		
						2	20	807	174
			V7 (WEEK 56)	2010-10-20	12:39	1	40		
						2	20	621	50
	016	4	SCREENING	2010-02-01	11:36	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	016	4	SCREENING	2010-02-01	11:36	2	20	691	143
			V1 (WEEK 0)	2010-03-01	10:56	1	40		
						2	20	602	140
			V3 (WEEK 12)	2010-05-19	10:19	1	40		
						2	20	605	102
			V4 (WEEK 24)	2010-08-09	11:38	1	40		
						2	20	522	115
			V5 (WEEK 36)	2010-11-08	11:02	1	40		
						2	20	632	158
	018	5	V6 (WEEK 52)	2011-02-28	11:58	1	40		
						2	20	614	125
			V7 (WEEK 56)	2011-04-07	12:47	1	40		
						2	20	539	102
			SCREENING	2009-11-03	12:59	1			
						2			
			V1 (WEEK 0)	2009-11-23	13:34	1	40		
						2	17	1477	271
			V3 (WEEK 12)	2010-02-16	11:44	1	40		
						2	20	802	216
			V4 (WEEK 24)	2010-05-11	11:56	1	47		
						2	8	1655	542
			V5 (WEEK 36)	2010-07-27	10:28	1	42		
						2	11	1566	286
			V6 (WEEK 52)	2010-11-23	12:08	1	44		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	018	5	V6 (WEEK 52)	2010-11-23	12:08	2	13	1612	463
			V7 (WEEK 56)	2010-12-14	11:04	1	42		
						2	13	1666	481
	020	5	SCREENING	2010-01-27	17:33	1	41		
						2	3	1537	869
			V1 (WEEK 0)	2010-02-22	12:56	1	41		
	024	4				2	8	1292	608
			SCREENING	2010-07-16	11:42	1	47		
						2	11	1663	523
			V1 (WEEK 0)	2010-08-16	10:54	1	43		
						2	16	1624	307
			V3 (WEEK 12)	2010-11-10	12:31	1	43		
						2	8	1502	430
			V4 (WEEK 24)	2011-02-02	11:22	1	41		
						2	20	849	204
			V5 (WEEK 36)	2011-04-18	11:11	1	42		
						2	15	1333	428
			V6 (WEEK 52)	2011-08-08	11:58	1	40		
						2	20	1003	245
	028	20	SCREENING	2010-11-18	11:48	1	40		
						2	20	910	162
			V1 (WEEK 0)	2010-11-26	10:18	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	028	20	V1 (WEEK 0)	2010-11-26	10:18	2	20	671	174
			V3 (WEEK 12)	2011-02-22	11:21	1	40		
						2	20	791	162
			V4 (WEEK 24)	2011-05-24	11:59	1	40		
						2	20	673	166
			V5 (WEEK 36)	2011-08-25	14:44	1	40		
						2	20	589	95
	029	8	V6 (WEEK 52)	2011-11-24	9:36	1	40		
						2	20	722	120
			V7 (WEEK 56)	2011-12-20	9:41	1	40		
						2	20	734	264
			SCREENING	2010-01-26	11:10	1	40		
						2	20	825	248
			V1 (WEEK 0)	2010-01-29	11:29	1	40		
						2	20	917	206
			V3 (WEEK 12)	2010-04-20	10:32	1	40		
						2	20	662	129
			V4 (WEEK 24)	2010-07-05	10:34	1	40		
						2	20	790	156
			V5 (WEEK 36)	2010-09-30	10:52	1	40		
						2	20	937	198
			V6 (WEEK 52)	2011-02-01	10:46	1	40		
						2	20	905	223
			V7 (WEEK 56)	2011-02-23	10:57	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	029	8	V7 (WEEK 56)	2011-02-23	10:57	2	19	777	208
			SCREENING	2010-05-06	12:54	1	40		
	031	8				2	20	862	226
			V1 (WEEK 0)	2010-05-20	10:51	1	40		
						2	20	735	137
			V3 (WEEK 12)	2010-08-17	11:27	1	40		
						2	20	777	115
			V4 (WEEK 24)	2010-11-09	10:13	1	40		
						2	20	800	129
			V5 (WEEK 36)	2011-01-25	10:42	1	40		
						2	20	762	149
			V6 (WEEK 52)	2011-05-17	12:51	1	40		
						2	20	786	162
			V7 (WEEK 56)	2011-06-14	11:11	1	40		
						2	20	717	128
	041	12	SCREENING	2009-09-23	12:21	1	40		
						2	20	589	148
			V1 (WEEK 0)	2009-10-09	11:56	1	40		
						2	20	608	71
			V3 (WEEK 12)	2010-01-05	14:16	1			
						2			
			V5 (WEEK 36)	2010-06-16	10:32	1			
						2			

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	041	12	V6 (WEEK 52)	2010-10-06	10:52	1	41		
						2	14	1348	536
			V7 (WEEK 56)	2010-11-03	9:26	1	40		
						2	20	613	87
	044	12	SCREENING	2009-11-04	11:49	1	41		
						2	20	845	424
			V1 (WEEK 0)	2009-12-02	11:17	1	40		
						2	20	844	257
			V3 (WEEK 12)	2010-02-24	12:14	1			
						2			
			V4 (WEEK 24)	2010-05-26	10:17	1	42		
						2	18	1110	515
			V5 (WEEK 36)	2010-08-18	12:27	1	42		
						2	20	1167	515
			V6 (WEEK 52)	2010-12-01	10:11	1	40		
						2	20	824	290
			V7 (WEEK 56)	2011-01-05	12:02	1	41		
						2	19	817	219
	045	11	SCREENING	2009-12-07	14:52	1	40		
						2	20	789	257
			V1 (WEEK 0)	2009-12-21	13:36	1	40		
						2	20	628	132
			V3 (WEEK 12)	2010-03-15	11:04	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	045	11	V3 (WEEK 12)	2010-03-15	11:04	2	20	630	179
			V4 (WEEK 24)	2010-06-07	12:14	1	40		
						2	20	550	103
			V5 (WEEK 36)	2010-09-06	12:35	1	40		
						2	20	559	127
			V6 (WEEK 52)	2010-12-15	12:04	1	40		
						2	20	719	107
	047	11	V7 (WEEK 56)	2011-01-17	12:16	1	40		
						2	20	742	178
			SCREENING	2010-07-12	12:01	1	40		
						2	20	601	87
			V1 (WEEK 0)	2010-08-02	13:21	1	40		
						2	20	679	103
			V3 (WEEK 12)	2010-10-20	14:43	1	43		
						2	20	527	62
			V4 (WEEK 24)	2011-01-10	12:18	1	40		
						2	20	561	71
			V5 (WEEK 36)	2011-04-12	12:20	1	40		
						2	20	560	58
			V6 (WEEK 52)	2011-07-27	12:15	1	40		
						2	20	497	37
			V7 (WEEK 56)	2011-08-29	10:03	1	40		
						2	20	500	50

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	049	21	SCREENING	2010-09-06	9:55	1	40		
						2	20	1175	315
			V1 (WEEK 0)	2010-10-27	10:29	1	44		
						2	15	1618	433
			V3 (WEEK 12)	2011-01-18	9:35	1	40		
						2	20	1197	162
			V4 (WEEK 24)	2011-04-12	9:31	1	40		
						2	20	1286	364
			V5 (WEEK 36)	2011-07-05	14:29	1	43		
						2	19	1529	377
	051	21	SCREENING	2010-09-06	11:46	1	40		
						2	20	687	131
			V1 (WEEK 0)	2010-10-28	13:27	1	40		
						2	20	878	240
			V3 (WEEK 12)	2011-02-01	8:58	1	40		
						2	20	652	169
			V4 (WEEK 24)	2011-04-12	14:37	1	41		
						2	20	748	136
			V5 (WEEK 36)	2011-07-05	15:44	1	40		
						2	20	725	218
			V6 (WEEK 52)	2011-10-25	10:13	1	40		
						2	20	798	312
			V7 (WEEK 56)	2011-11-22	9:17	1	40		
						2	20	671	109

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	056	5	SCREENING	2010-03-31	12:05	1	40		
						2	20	699	112
			V1 (WEEK 0)	2010-04-21	10:47	1	40		
						2	20	650	138
			V4 (WEEK 24)	2010-10-05	11:35	1	40		
						2	20	551	90
			V5 (WEEK 36)	2011-01-04	11:03	1	40		
						2	20	808	162
	065	16	SCREENING	2010-08-10	13:02	1	40		
						2	20	623	135
			V1 (WEEK 0)	2010-08-30	13:31	1	46		
						2	11	1700	468
			V3 (WEEK 12)	2010-11-22	10:13	1	40		
						2	20	791	101
			V4 (WEEK 24)	2011-01-17	12:33	1	41		
						2	20	873	317
	068	16	SCREENING	2010-10-26	10:50	1	40		
						2	20	1212	349
			V1 (WEEK 0)	2010-11-22	11:39	1	40		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	068	16	V1 (WEEK 0)	2010-11-22	11:39	2	20	785	118
			V3 (WEEK 12)	2011-02-10	10:43	1	41		
						2	19	1000	325
			V4 (WEEK 24)	2011-05-03	11:38	1	40		
						2	20	1077	235
			V5 (WEEK 36)	2011-08-10	9:59	1	40		
						2	20	987	129
	069	23	V6 (WEEK 52)	2011-11-28	13:21	1	40		
						2	20	1268	314
			SCREENING	2010-11-24	11:05	1	40		
						2	20	938	249
			V1 (WEEK 0)	2010-12-07	13:46	1	40		
						2	20	682	120
			V3 (WEEK 12)	2011-03-09	11:30	1	40		
						2	20	619	146
			V4 (WEEK 24)	2011-05-19	10:53	1	40		
						2	20	706	134
			V5 (WEEK 36)	2011-08-24	11:08	1	40		
						2	20	503	63
			V6 (WEEK 52)	2011-12-14	11:09	1	40		
						2	18	1032	517
			V7 (WEEK 56)	2012-01-11	11:13	1	43		
						2	17	598	102

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	072	18	SCREENING	2010-12-01	0:44	1	40		
						2	20	823	287
			V1 (WEEK 0)	2010-12-21	0:40	1	40		
						2	20	822	185
			V3 (WEEK 12)	2011-03-15	10:08	1	41		
						2	18	611	237
			V4 (WEEK 24)	2011-06-07	11:02	1	40		
						2	20	860	246
			V5 (WEEK 36)	2011-09-08	11:40	1	40		
						2	19	951	279
			V6 (WEEK 52)	2011-12-15	10:51	1	40		
						2	20	805	223
			V7 (WEEK 56)	2012-01-17	13:00	1	40		
						2	20	670	188
	079	13	SCREENING	2010-07-19	14:00	1	43		
						2	13	1541	459
			V1 (WEEK 0)	2010-08-06	12:30	1	40		
						2	18	1493	375
			V3 (WEEK 12)	2010-11-16	13:26	1	43		
						2	13	1637	530
			V4 (WEEK 24)	2011-01-27	12:48	1	44		
						2	18	1692	540
			V5 (WEEK 36)	2011-04-11	13:58	1	43		
						2	19	1580	398

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	079	13	V6 (WEEK 52)	2011-06-21	14:23	1	48		
						2	18	1592	334
			V7 (WEEK 56)	2011-07-19	13:16	1	44		
						2	16	1479	394
	082	17	SCREENING	2010-10-06	21:10	1			
						2			
			V1 (WEEK 0)	2010-10-14	9:32	1	41		
						2	20	772	416
			V3 (WEEK 12)	2011-01-05	13:03	1	40		
						2	20	568	103
			V4 (WEEK 24)	2011-04-06	13:13	1	40		
						2	20	532	116
			V5 (WEEK 36)	2011-06-22		1	40		
						2	18	1098	443
			V6 (WEEK 52)	2011-10-12		1	43		
						2	16	1024	564
			V7 (WEEK 56)	2011-11-24		1	40		
						2	18	1011	412
	084	17	SCREENING	2010-11-08	21:44	1	40		
						2	16	1109	312
			V1 (WEEK 0)	2010-04-21	12:21	1	43		
						2	18	897	458
			V3 (WEEK 12)	2011-02-08	14:28	1	48		

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	084	17	V3 (WEEK 12)	2011-02-08	14:28	2	22	727	261
			V4 (WEEK 24)	2011-05-10	14:39	1	41		
						2	17	1229	585
			V5 (WEEK 36)	2011-08-02		1			
						2			
			V6 (WEEK 52)	2011-11-22		1	45		
						2	9	981	496
	086	21	V7 (WEEK 56)	2011-12-15		1	42		
						2	10	1164	473
			SCREENING	2010-10-04	9:42	1	40		
						2	19	974	398
			V1 (WEEK 0)	2010-10-28	15:39	1	41		
						2	14	959	438
			V3 (WEEK 12)	2011-01-18	12:53	1	40		
						2	15	650	241
			V4 (WEEK 24)	2011-04-12	13:06	1	43		
						2	16	1304	478
			V5 (WEEK 36)	2011-07-05	13:18	1	40		
						2	20	788	217
			V6 (WEEK 52)	2011-10-25	12:40	1	41		
						2	19	724	132
			V7 (WEEK 56)	2011-11-22	11:26	1	40		
						2	20	720	184

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Listing 16.2.6.7: Choice Reaction Time - MSO (Maximum Stimulatory Output)

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Treat- ment	Random No.	Site ID	Visit	Date	Time	Doc list	Number of trials	Reaction time	Standard deviation
Placebo	088	16	SCREENING	2010-11-30	11:27	1	40		
						2	20	706	138
			V1 (WEEK 0)	2010-12-09	10:08	1	40		
						2	20	603	126
			V3 (WEEK 12)	2011-03-01	10:46	1	40		
						2	20	806	178

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	002	46	1	SCREENING	7		3		10	
				V1 (WEEK 0)	10		7		17	
				V3 (WEEK 12)	11	1	5	-2	16	-1
				V4 (WEEK 24)	10	0	5	-2	15	-2
				V5 (WEEK 36)	9	-1	0	-7	9	-8
				V6 (WEEK 52)	11	1	0	-7	11	-6
				V7 (WEEK 56)	9	-1	0	-7	9	-8
	004	47	1	SCREENING	8		0		8	
				V1 (WEEK 0)	12		0		12	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	006	8	2	SCREENING	11		2		13	
				V1 (WEEK 0)	9		0		9	
				V3 (WEEK 12)	11	2	1	1	12	3
				V4 (WEEK 24)	9	0	2	2	11	2

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	002	46	1	SCREENING	10		5		15	
				V1 (WEEK 0)	12		7		19	
				V3 (WEEK 12)	12	0	7	0	19	0
				V4 (WEEK 24)	12	0	11	4	23	4
				V5 (WEEK 36)	12	0	1	-6	13	-6
				V6 (WEEK 52)	12	0	1	-6	13	-6
				V7 (WEEK 56)	12	0	1	-6	13	-6
	004	47	1	SCREENING	11		0		11	
				V1 (WEEK 0)	12		1		13	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	006	8	2	SCREENING	12		6		18	
				V1 (WEEK 0)	12		5		17	
				V3 (WEEK 12)	12	0	5	0	17	0
				V4 (WEEK 24)	11	-1	5	0	16	-1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	006	8	2	V5 (WEEK 36)	9	0	0	0	9	0
				V6 (WEEK 52)	10	1	1	1	11	2
				V7 (WEEK 56)	11	2	0	0	11	2
	010	10	1	SCREENING	11		0		11	
				V1 (WEEK 0)	7		5		12	
				V3 (WEEK 12)	9	2	0	-5	9	-3
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	012	67	1	SCREENING	7		0		7	
				V1 (WEEK 0)	8		0		8	
				V3 (WEEK 12)	10	2	0	0	10	2
				V4 (WEEK 24)	8	0	0	0	8	0
				V5 (WEEK 36)						
				V6 (WEEK 52)	7	-1	0	0	7	-1
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	006	8	2	V5 (WEEK 36)	12	0	2	-3	14	-3
				V6 (WEEK 52)	10	-2	2	-3	12	-5
				V7 (WEEK 56)	12	0	3	-2	15	-2
	010	10	1	SCREENING	12		1		13	
				V1 (WEEK 0)	0		0		0	
				V3 (WEEK 12)	9	9	3	3	12	12
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	012	67	1	SCREENING	11		1		12	
				V1 (WEEK 0)	11		1		12	
				V3 (WEEK 12)	10	-1	1	0	11	-1
				V4 (WEEK 24)	11	0	1	0	12	0
				V5 (WEEK 36)						
				V6 (WEEK 52)	11	0	1	0	12	0
				V7 (WEEK 56)						

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	014	22	4	SCREENING	4		2		6	
				V1 (WEEK 0)	10		2		12	
				V3 (WEEK 12)	11	1	0	-2	11	-1
				V4 (WEEK 24)	12	2	2	0	14	2
				V5 (WEEK 36)	12	2	0	-2	12	0
				V6 (WEEK 52)	12	2	3	1	15	3
				V7 (WEEK 56)	12	2	2	0	14	2
	015	23	4	SCREENING	8		0		8	
				V1 (WEEK 0)	10		0		10	
				V3 (WEEK 12)	8	-2	0	0	8	-2
				V4 (WEEK 24)	8	-2	1	1	9	-1
				V5 (WEEK 36)	8	-2	0	0	8	-2
				V6 (WEEK 52)	9	-1	0	0	9	-1
				V7 (WEEK 56)	12	2	0	0	12	2
	017	17	5	SCREENING	4		1		5	
				V1 (WEEK 0)	11		0		11	
				V3 (WEEK 12)	8	-3	0	0	8	-3
				V4 (WEEK 24)	3	-8	2	2	5	-6

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	014	22	4	SCREENING	9		5		14	
				V1 (WEEK 0)	10		2		12	
				V3 (WEEK 12)	12	2	3	1	15	3
				V4 (WEEK 24)	10	0	6	4	16	4
				V5 (WEEK 36)	12	2	5	3	17	5
				V6 (WEEK 52)	12	2	5	3	17	5
				V7 (WEEK 56)	12	2	3	1	15	3
	015	23	4	SCREENING	9		3		12	
				V1 (WEEK 0)	11		1		12	
				V3 (WEEK 12)	10	-1	1	0	11	-1
				V4 (WEEK 24)	10	-1	1	0	11	-1
				V5 (WEEK 36)	11	0	1	0	12	0
				V6 (WEEK 52)	9	-2	1	0	10	-2
				V7 (WEEK 56)	12	1	1	0	13	1
	017	17	5	SCREENING	8		1		9	
				V1 (WEEK 0)	12		1		13	
				V3 (WEEK 12)	10	-2	1	0	11	-2
				V4 (WEEK 24)	9	-3	1	0	10	-3

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	017	17	5	V5 (WEEK 36)	11	0	0	0	11	0
				V6 (WEEK 52)	9	-2	0	0	9	-2
				V7 (WEEK 56)	11	0	0	0	11	0
	019	19	5	SCREENING	9		1		10	
				V1 (WEEK 0)	10		2		12	
				V3 (WEEK 12)	9	-1	1	-1	10	-2
				V4 (WEEK 24)	12	2	1	-1	13	1
				V5 (WEEK 36)	10	0	1	-1	11	-1
				V6 (WEEK 52)	11	1	1	-1	12	0
				V7 (WEEK 56)	12	2	1	-1	13	1
	023	71	4	SCREENING	3		0		3	
				V1 (WEEK 0)	8		0		8	
				V3 (WEEK 12)	2	-6	0	0	2	-6
				V4 (WEEK 24)	2	-6	0	0	2	-6
				V5 (WEEK 36)	3	-5	0	0	3	-5
				V6 (WEEK 52)	1	-7	0	0	1	-7
				V7 (WEEK 56)	2	-6	0	0	2	-6

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	017	17	5	V5 (WEEK 36)	12	0	1	0	13	0
				V6 (WEEK 52)	10	-2	1	0	11	-2
				V7 (WEEK 56)	12	0	1	0	13	0
	019	19	5	SCREENING	12		4		16	
				V1 (WEEK 0)	10		2		12	
				V3 (WEEK 12)	10	0	2	0	12	0
				V4 (WEEK 24)	11	1	1	-1	12	0
				V5 (WEEK 36)	12	2	2	0	14	2
				V6 (WEEK 52)	12	2	4	2	16	4
				V7 (WEEK 56)	12	2	1	-1	13	1
	023	71	4	SCREENING	6		0		6	
				V1 (WEEK 0)	12		1		13	
				V3 (WEEK 12)	3	-9	1	0	4	-9
				V4 (WEEK 24)	2	-10	0	-1	2	-11
				V5 (WEEK 36)	6	-6	0	-1	6	-7
				V6 (WEEK 52)	2	-10	1	0	3	-10
				V7 (WEEK 56)	3	-9	1	0	4	-9

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	027	87	20	SCREENING	12		6		18	
				V1 (WEEK 0)	11		7		18	
				V3 (WEEK 12)	9	-2	5	-2	14	-4
				V4 (WEEK 24)	11	0	7	0	18	0
				V5 (WEEK 36)	12	1	5	-2	17	-1
				V6 (WEEK 52)	11	0	8	1	19	1
				V7 (WEEK 56)	12	1	6	-1	18	0
	030	50	8	SCREENING	9		1		10	
				V1 (WEEK 0)	9		3		12	
				V3 (WEEK 12)	9	0	2	-1	11	-1
				V4 (WEEK 24)	8	-1	2	-1	10	-2
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)	7	-2	1	-2	8	-4
	032	52	8	SCREENING	4		0		4	
				V1 (WEEK 0)	5		1		6	
				V3 (WEEK 12)						
				V4 (WEEK 24)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	027	87	20	SCREENING	8		7		15	
				V1 (WEEK 0)						
				V3 (WEEK 12)	11		9		20	
				V4 (WEEK 24)						
				V5 (WEEK 36)	12		9		21	
				V6 (WEEK 52)						
				V7 (WEEK 56)	12		9		21	
	030	50	8	SCREENING	11		2		13	
				V1 (WEEK 0)	10		1		11	
				V3 (WEEK 12)	10	0	2	1	12	1
				V4 (WEEK 24)	10	0	0	-1	10	-1
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)	10	0	1	0	11	0
	032	52	8	SCREENING	5		2		7	
				V1 (WEEK 0)	8		2		10	
				V3 (WEEK 12)						
				V4 (WEEK 24)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	032	52	8	V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	033	33	9	SCREENING	11		8		19	
				V1 (WEEK 0)	12		9		21	
				V3 (WEEK 12)	6	-6	7	-2	13	-8
				V4 (WEEK 24)	10	-2	8	-1	18	-3
				V5 (WEEK 36)	11	-1	7	-2	18	-3
				V6 (WEEK 52)	11	-1	9	0	20	-1
				V7 (WEEK 56)	9	-3	8	-1	17	-4
	042	70	12	SCREENING	2		0		2	
				V1 (WEEK 0)	6		1		7	
				V3 (WEEK 12)	2	-4	0	-1	2	-5
				V4 (WEEK 24)	4	-2	0	-1	4	-3
				V5 (WEEK 36)	3	-3	0	-1	3	-4
				V6 (WEEK 52)	1	-5	1	0	2	-5
				V7 (WEEK 56)	1	-5	0	-1	1	-6

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	032	52	8	V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	033	33	9	SCREENING						
				V1 (WEEK 0)	4		4		8	
				V3 (WEEK 12)	12	0	11	-1	23	-1
				V4 (WEEK 24)	12	0	12	0	24	0
				V5 (WEEK 36)	11	-1	11	-1	22	-2
				V6 (WEEK 52)						
				V7 (WEEK 56)	11	0	11	0	22	0
	042	70	12	SCREENING	3		1		4	
				V1 (WEEK 0)	8		1		9	
				V3 (WEEK 12)	6	-2	1	0	7	-2
				V4 (WEEK 24)	8	0	1	0	9	0
				V5 (WEEK 36)	5	-3	1	0	6	-3
				V6 (WEEK 52)	4	-4	0	-1	4	-5
				V7 (WEEK 56)	0	-8	0	-1	0	-9

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	043	43	12	SCREENING	8		1		9	
				V1 (WEEK 0)	10		0		10	
				V3 (WEEK 12)	7	-3	0	0	7	-3
				V4 (WEEK 24)	4	-6	0	0	4	-6
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	046	62	11	SCREENING	5		0		5	
				V1 (WEEK 0)						
				V3 (WEEK 12)	6		0		6	
				V4 (WEEK 24)	7		0		7	
				V5 (WEEK 36)	10		0		10	
				V6 (WEEK 52)	11		0		11	
				V7 (WEEK 56)	9		0		9	
	048	104	11	SCREENING	5		0		5	
				V1 (WEEK 0)	9		5		14	
				V3 (WEEK 12)	12	3	1	-4	13	-1
				V4 (WEEK 24)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	043	43	12	SCREENING	9		2		11	
				V1 (WEEK 0)	11		1		12	
				V3 (WEEK 12)	8	-3	1	0	9	-3
				V4 (WEEK 24)	6	-5	0	-1	6	-6
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	046	62	11	SCREENING	7		1		8	
				V1 (WEEK 0)						
				V3 (WEEK 12)	7		1		8	
				V4 (WEEK 24)	11		1		12	
				V5 (WEEK 36)	12		2		14	
				V6 (WEEK 52)	8		0		8	
				V7 (WEEK 56)	9		1		10	
	048	104	11	SCREENING	9		3		12	
				V1 (WEEK 0)	11		5		16	
				V3 (WEEK 12)	12	1	9	4	21	5
				V4 (WEEK 24)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	048	104	11	V5 (WEEK 36)	11	2	4	-1	15	1
				V6 (WEEK 52)	11	2	1	-4	12	-2
				V7 (WEEK 56)	12	3	3	-2	15	1
	050	93	21	SCREENING	5		2		7	
				V1 (WEEK 0)	6		1		7	
				V3 (WEEK 12)	10	4	2	1	12	5
				V4 (WEEK 24)	12	6	1	0	13	6
				V5 (WEEK 36)	12	6	2	1	14	7
				V6 (WEEK 52)	10	4	2	1	12	5
				V7 (WEEK 56)	12	6	2	1	14	7
	052	91	21	SCREENING	9		0		9	
				V1 (WEEK 0)	8		0		8	
				V3 (WEEK 12)	8	0	0	0	8	0
				V4 (WEEK 24)	9	1	0	0	9	1
				V5 (WEEK 36)	12	4	0	0	12	4
				V6 (WEEK 52)	10	2	0	0	10	2
				V7 (WEEK 56)	11	3	0	0	11	3

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	048	104	11	V5 (WEEK 36)	12	1	8	3	20	4
				V6 (WEEK 52)	12	1	6	1	18	2
				V7 (WEEK 56)	12	1	6	1	18	2
	050	93	21	SCREENING	12		4		16	
				V1 (WEEK 0)	10		2		12	
				V3 (WEEK 12)	12	2	4	2	16	4
				V4 (WEEK 24)	12	2	3	1	15	3
				V5 (WEEK 36)	12	2	4	2	16	4
				V6 (WEEK 52)	12	2	4	2	16	4
				V7 (WEEK 56)	12	2	4	2	16	4
	052	91	21	SCREENING	8		0		8	
				V1 (WEEK 0)	10		1		11	
				V3 (WEEK 12)	10	0	0	-1	10	-1
				V4 (WEEK 24)	12	2	1	0	13	2
				V5 (WEEK 36)	12	2	0	-1	12	1
				V6 (WEEK 52)	12	2	1	0	13	2
				V7 (WEEK 56)	12	2	1	0	13	2

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	055	76	5	SCREENING	10		2		12	
				V1 (WEEK 0)	12		2		14	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)	12	0	1	-1	13	-1
				V7 (WEEK 56)						
	057	68	1	SCREENING	10		0		10	
				V1 (WEEK 0)	8		0		8	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	066	83	16	SCREENING	11		4		15	
				V1 (WEEK 0)	12		8		20	
				V3 (WEEK 12)	3	-9	0	-8	3	-17
				V4 (WEEK 24)						

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	055	76	5	SCREENING	9		7		16	
				V1 (WEEK 0)	12		6		18	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)	12	0	1	-5	13	-5
				V7 (WEEK 56)						
	057	68	1	SCREENING	12		4		16	
				V1 (WEEK 0)	10		1		11	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	066	83	16	SCREENING	11		6		17	
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	066	83	16	V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	067	38	16	SCREENING	11		9		20	
				V1 (WEEK 0)	12		11		23	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	071	105	18	SCREENING	4		0		4	
				V1 (WEEK 0)	5		0		5	
				V3 (WEEK 12)	9	4	1	1	10	5
				V4 (WEEK 24)	6	1	0	0	6	1
				V5 (WEEK 36)	10	5	0	0	10	5
				V6 (WEEK 52)						
				V7 (WEEK 56)	3	-2	0	0	3	-2

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	066	83	16	V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	067	38	16	SCREENING						
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	071	105	18	SCREENING	2		0		2	
				V1 (WEEK 0)	10		1		11	
				V3 (WEEK 12)	10	0	1	0	11	0
				V4 (WEEK 24)	12	2	0	-1	12	1
				V5 (WEEK 36)	12	2	1	0	13	2
				V6 (WEEK 52)						
				V7 (WEEK 56)	7	-3	1	0	8	-3

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	080	59	13	SCREENING	12		2		14	
				V1 (WEEK 0)	9		3		12	
				V3 (WEEK 12)	9	0	4	1	13	1
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	081	25	17	SCREENING	8		6		14	
				V1 (WEEK 0)	7		6		13	
				V3 (WEEK 12)	10	3	8	2	18	5
				V4 (WEEK 24)	9	2	4	-2	13	0
				V5 (WEEK 36)	6	-1	5	-1	11	-2
				V6 (WEEK 52)	3	-4	3	-3	6	-7
				V7 (WEEK 56)	7	0	3	-3	10	-3
	083	27	17	SCREENING	5		6		11	
				V1 (WEEK 0)	7		5		12	
				V3 (WEEK 12)	6	-1	7	2	13	1
				V4 (WEEK 24)	6	-1	6	1	12	0

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	080	59	13	SCREENING	11		4		15	
				V1 (WEEK 0)	11		3		14	
				V3 (WEEK 12)	9	-2	8	5	17	3
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	081	25	17	SCREENING	4		4		8	
				V1 (WEEK 0)	11		8		19	
				V3 (WEEK 12)						
				V4 (WEEK 24)	12	1	10	2	22	3
				V5 (WEEK 36)	10	-1	10	2	20	1
				V6 (WEEK 52)	9	-2	6	-2	15	-4
				V7 (WEEK 56)	11	0	8	0	19	0
	083	27	17	SCREENING	11		9		20	
				V1 (WEEK 0)	11		10		21	
				V3 (WEEK 12)	10	-1	11	1	21	0
				V4 (WEEK 24)	12	1	8	-2	20	-1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	083	27	17	V5 (WEEK 36)	5	-2	3	-2	8	-4
				V6 (WEEK 52)	7	0	7	2	14	2
				V7 (WEEK 56)	7	0	6	1	13	1
	087	39	16	SCREENING	10		6		16	
				V1 (WEEK 0)	12		7		19	
				V3 (WEEK 12)	1	-11	2	-5	3	-16
				V4 (WEEK 24)	8	-4	5	-2	13	-6
				V5 (WEEK 36)	7	-5	4	-3	11	-8
				V6 (WEEK 52)	11	-1	4	-3	15	-4
				V7 (WEEK 56)	5	-7	3	-4	8	-11
		54	16	V3 (WEEK 12)	11		4		15	
	089	74	5	SCREENING	8		1		9	
				V1 (WEEK 0)	3		0		3	
				V3 (WEEK 12)	6	3	2	2	8	5
				V4 (WEEK 24)						
				V5 (WEEK 36)	3	0	0	0	3	0
				V6 (WEEK 52)	5	2	0	0	5	2
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	083	27	17	V5 (WEEK 36)	11	0	5	-5	16	-5
				V6 (WEEK 52)	10	-1	10	0	20	-1
				V7 (WEEK 56)	11	0	9	-1	20	-1
	087	39	16	SCREENING	11		8		19	
				V1 (WEEK 0)						
				V3 (WEEK 12)	6		1		7	
				V4 (WEEK 24)	12		5		17	
				V5 (WEEK 36)	12		7		19	
				V6 (WEEK 52)	11		7		18	
				V7 (WEEK 56)	9		3		12	
		54	16	V3 (WEEK 12)	4		4		8	
	089	74	5	SCREENING	0		0		0	
				V1 (WEEK 0)	4		1		5	
				V3 (WEEK 12)	3	-1	1	0	4	-1
				V4 (WEEK 24)						
				V5 (WEEK 36)	3	-1	0	-1	3	-2
				V6 (WEEK 52)						
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	093	29	17	SCREENING	6		2		8	
				V1 (WEEK 0)	9		6		15	
				V3 (WEEK 12)	7	-2	5	-1	12	-3
				V4 (WEEK 24)	9	0	6	0	15	0
				V5 (WEEK 36)	6	-3	3	-3	9	-6
				V6 (WEEK 52)	6	-3	6	0	12	-3
				V7 (WEEK 56)	8	-1	6	0	14	-1
	097	69	12	SCREENING	4		1		5	
				V1 (WEEK 0)	1		1		2	
				V3 (WEEK 12)	3	2	1	0	4	2
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
Placebo	001	48	1	SCREENING	7		0		7	
				V1 (WEEK 0)	11		0		11	
				V3 (WEEK 12)	7	-4	0	0	7	-4
				V4 (WEEK 24)	11	0	1	1	12	1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
ACI-91	093	29	17	SCREENING	11		7		18	
				V1 (WEEK 0)	11		9		20	
				V3 (WEEK 12)	9	-2	8	-1	17	-3
				V4 (WEEK 24)	11	0	9	0	20	0
				V5 (WEEK 36)	12	1	8	-1	20	0
				V6 (WEEK 52)	10	-1	6	-3	16	-4
				V7 (WEEK 56)	11	0	5	-4	16	-4
	097	69	12	SCREENING	7		1		8	
				V1 (WEEK 0)	0		1		1	
				V3 (WEEK 12)	2	2	0	-1	2	1
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
Placebo	001	48	1	SCREENING	8		1		9	
				V1 (WEEK 0)	12		0		12	
				V3 (WEEK 12)	7	-5	0	0	7	-5
				V4 (WEEK 24)	12	0	3	3	15	3

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	001	48	1	V5 (WEEK 36)	4	-7	0	0	4	-7
				V6 (WEEK 52)						
				V7 (WEEK 56)	4	-7	0	0	4	-7
	003	45	1	SCREENING	9		0		9	
				V1 (WEEK 0)	9		0		9	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	005	5	2	SCREENING	12		2		14	
				V1 (WEEK 0)	12		7		19	
				V3 (WEEK 12)	12	0	6	-1	18	-1
				V4 (WEEK 24)	12	0	8	1	20	1
				V5 (WEEK 36)	12	0	6	-1	18	-1
				V6 (WEEK 52)	9	-3	4	-3	13	-6
				V7 (WEEK 56)	12	0	8	1	20	1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	001	48	1	V5 (WEEK 36)	5	-7	0	0	5	-7
				V6 (WEEK 52)						
				V7 (WEEK 56)	5	-7	0	0	5	-7
	003	45	1	SCREENING	11		0		11	
				V1 (WEEK 0)	12		2		14	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	005	5	2	SCREENING	8		7		15	
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)	12		8		20	
				V6 (WEEK 52)	12		7		19	
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	009	11	1	SCREENING	10		0		10	
				V1 (WEEK 0)	4		0		4	
				V3 (WEEK 12)	9	5	0	0	9	5
				V4 (WEEK 24)	9	5	0	0	9	5
				V5 (WEEK 36)	8	4	0	0	8	4
				V6 (WEEK 52)	9	5	0	0	9	5
				V7 (WEEK 56)	5	1	0	0	5	1
	011	65	1	SCREENING	3		0		3	
				V1 (WEEK 0)	7		0		7	
				V3 (WEEK 12)	6	-1	0	0	6	-1
				V4 (WEEK 24)	10	3	0	0	10	3
				V5 (WEEK 36)	10	3	0	0	10	3
				V6 (WEEK 52)	6	-1	0	0	6	-1
				V7 (WEEK 56)	8	1	0	0	8	1
	013	21	4	SCREENING	5		0		5	
				V1 (WEEK 0)	8		0		8	
				V3 (WEEK 12)	8	0	0	0	8	0
				V4 (WEEK 24)	9	1	0	0	9	1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	009	11	1	SCREENING	11		0		11	
				V1 (WEEK 0)	8		0		8	
				V3 (WEEK 12)	11	3	1	1	12	4
				V4 (WEEK 24)	11	3	1	1	12	4
				V5 (WEEK 36)	10	2	1	1	11	3
				V6 (WEEK 52)	11	3	0	0	11	3
				V7 (WEEK 56)	7	-1	0	0	7	-1
	011	65	1	SCREENING	5		0		5	
				V1 (WEEK 0)	9		0		9	
				V3 (WEEK 12)	10	1	1	1	11	2
				V4 (WEEK 24)	12	3	1	1	13	4
				V5 (WEEK 36)	10	1	0	0	10	1
				V6 (WEEK 52)	8	-1	1	1	9	0
				V7 (WEEK 56)	10	1	1	1	11	2
	013	21	4	SCREENING	9		1		10	
				V1 (WEEK 0)	8		1		9	
				V3 (WEEK 12)	9	1	0	-1	9	0
				V4 (WEEK 24)	9	1	1	0	10	1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	013	21	4	V5 (WEEK 36)	8	0	0	0	8	0
				V6 (WEEK 52)	8	0	0	0	8	0
				V7 (WEEK 56)	9	1	1	1	10	2
	016	24	4	SCREENING	12		5		17	
				V1 (WEEK 0)	10		10		20	
				V3 (WEEK 12)	12	2	10	0	22	2
				V4 (WEEK 24)	11	1	9	-1	20	0
				V5 (WEEK 36)	11	1	10	0	21	1
				V6 (WEEK 52)	11	1	5	-5	16	-4
				V7 (WEEK 56)	11	1	5	-5	16	-4
	018	18	5	SCREENING	1		0		1	
				V1 (WEEK 0)	1		0		1	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)	0	-1	0	0	0	-1
				V6 (WEEK 52)	0	-1	0	0	0	-1
				V7 (WEEK 56)	0	-1	0	0	0	-1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	013	21	4	V5 (WEEK 36)	9	1	2	1	11	2
				V6 (WEEK 52)	10	2	1	0	11	2
				V7 (WEEK 56)	10	2	1	0	11	2
	016	24	4	SCREENING						
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)	12		8		20	
				V5 (WEEK 36)						
				V6 (WEEK 52)	12		7		19	
				V7 (WEEK 56)	12		7		19	
	018	18	5	SCREENING	0		1		1	
				V1 (WEEK 0)	3		0		3	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)	0	-3	0	0	0	-3
				V6 (WEEK 52)						
				V7 (WEEK 56)	0	-3	0	0	0	-3

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	020	20	5	SCREENING	3		0		3	
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	024	72	4	SCREENING	9		0		9	
				V1 (WEEK 0)	11		4		15	
				V3 (WEEK 12)	11	0	1	-3	12	-3
				V4 (WEEK 24)	9	-2	4	0	13	-2
				V5 (WEEK 36)	12	1	1	-3	13	-2
				V6 (WEEK 52)	12	1	3	-1	15	0
				V7 (WEEK 56)	12	1	2	-2	14	-1
	028	88	20	SCREENING	2		0		2	
				V1 (WEEK 0)	2		0		2	
				V3 (WEEK 12)	1	-1	0	0	1	-1
				V4 (WEEK 24)	1	-1	0	0	1	-1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	020	20	5	SCREENING	2		0		2	
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	024	72	4	SCREENING	12		1		13	
				V1 (WEEK 0)	12		7		19	
				V3 (WEEK 12)	12	0	8	1	20	1
				V4 (WEEK 24)	12	0	5	-2	17	-2
				V5 (WEEK 36)	12	0	3	-4	15	-4
				V6 (WEEK 52)	12	0	2	-5	14	-5
				V7 (WEEK 56)	12	0	4	-3	16	-3
	028	88	20	SCREENING	2		1		3	
				V1 (WEEK 0)	4		1		5	
				V3 (WEEK 12)	2	-2	0	-1	2	-3
				V4 (WEEK 24)	0	-4	1	0	1	-4

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	028	88	20	V5 (WEEK 36)	2	0	0	0	2	0
				V6 (WEEK 52)	0	-2	0	0	0	-2
				V7 (WEEK 56)	1	-1	0	0	1	-1
	029	49	8	SCREENING	11		3		14	
				V1 (WEEK 0)	11		11		22	
				V3 (WEEK 12)	11	0	5	-6	16	-6
				V4 (WEEK 24)	12	1	6	-5	18	-4
				V5 (WEEK 36)	10	-1	7	-4	17	-5
				V6 (WEEK 52)	12	1	7	-4	19	-3
				V7 (WEEK 56)	12	1	6	-5	18	-4
	031	51	8	SCREENING	4		0		4	
				V1 (WEEK 0)	5		2		7	
				V3 (WEEK 12)	7	2	0	-2	7	0
				V4 (WEEK 24)	7	2	0	-2	7	0
				V5 (WEEK 36)	7	2	0	-2	7	0
				V6 (WEEK 52)	7	2	0	-2	7	0
				V7 (WEEK 56)	7	2	1	-1	8	1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	028	88	20	V5 (WEEK 36)	1	-3	1	0	2	-3
				V6 (WEEK 52)	0	-4	1	0	1	-4
				V7 (WEEK 56)	0	-4	1	0	1	-4
	029	49	8	SCREENING	12		8		20	
				V1 (WEEK 0)						
				V3 (WEEK 12)	4		4		8	
				V4 (WEEK 24)	12		6		18	
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	031	51	8	SCREENING	5		1		6	
				V1 (WEEK 0)	6		2		8	
				V3 (WEEK 12)	7	1	1	-1	8	0
				V4 (WEEK 24)	7	1	1	-1	8	0
				V5 (WEEK 36)	7	1	2	0	9	1
				V6 (WEEK 52)	9	3	1	-1	10	2
				V7 (WEEK 56)	10	4	1	-1	11	3

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	034	34	9	SCREENING	1		0		1	
				V1 (WEEK 0)	9		0		9	
				V3 (WEEK 12)	8	-1	0	0	8	-1
				V4 (WEEK 24)	5	-4	0	0	5	-4
				V5 (WEEK 36)	7	-2	0	0	7	-2
				V6 (WEEK 52)	5	-4	0	0	5	-4
				V7 (WEEK 56)	3	-6	0	0	3	-6
	041	41	12	SCREENING	3		0		3	
				V1 (WEEK 0)	6		0		6	
				V3 (WEEK 12)	5	-1	0	0	5	-1
				V4 (WEEK 24)	9	3	0	0	9	3
				V5 (WEEK 36)	7	1	0	0	7	1
				V6 (WEEK 52)	7	1	0	0	7	1
				V7 (WEEK 56)	10	4	0	0	10	4
	044	44	12	SCREENING	6		0		6	
				V1 (WEEK 0)	6		1		7	
				V3 (WEEK 12)	10	4	0	-1	10	3
				V4 (WEEK 24)	9	3	2	1	11	4

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	034	34	9	SCREENING						
				V1 (WEEK 0)	8		2		10	
				V3 (WEEK 12)	6	-2	5	3	11	1
				V4 (WEEK 24)	4	-4	0	-2	4	-6
				V5 (WEEK 36)	9	1	0	-2	9	-1
				V6 (WEEK 52)	6	-2	1	-1	7	-3
				V7 (WEEK 56)	9	1	1	-1	10	0
	041	41	12	SCREENING	7		1		8	
				V1 (WEEK 0)	9		1		10	
				V3 (WEEK 12)	7	-2	1	0	8	-2
				V4 (WEEK 24)	5	-4	1	0	6	-4
				V5 (WEEK 36)	8	-1	0	-1	8	-2
				V6 (WEEK 52)	8	-1	1	0	9	-1
				V7 (WEEK 56)	10	1	1	0	11	1
	044	44	12	SCREENING	11		1		12	
				V1 (WEEK 0)	8		1		9	
				V3 (WEEK 12)	11	3	1	0	12	3
				V4 (WEEK 24)	8	0	1	0	9	0

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	044	44	12	V5 (WEEK 36)	8	2	1	0	9	2
				V6 (WEEK 52)	8	2	1	0	9	2
				V7 (WEEK 56)	7	1	1	0	8	1
	045	61	11	SCREENING	8		4		12	
				V1 (WEEK 0)	9		8		17	
				V3 (WEEK 12)	10	1	5	-3	15	-2
				V4 (WEEK 24)	11	2	8	0	19	2
				V5 (WEEK 36)	10	1	6	-2	16	-1
				V6 (WEEK 52)	8	-1	3	-5	11	-6
				V7 (WEEK 56)	12	3	7	-1	19	2
	047	64	11	SCREENING						
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	044	44	12	V5 (WEEK 36)	8	0	1	0	9	0
				V6 (WEEK 52)	7	-1	1	0	8	-1
				V7 (WEEK 56)	7	-1	1	0	8	-1
	045	61	11	SCREENING	4		4		8	
				V1 (WEEK 0)	8		7		15	
				V3 (WEEK 12)	8	0	7	0	15	0
				V4 (WEEK 24)	7	-1	8	1	15	0
				V5 (WEEK 36)	12	0	8	-1	20	-1
				V6 (WEEK 52)	11	-1	6	-3	17	-4
				V7 (WEEK 56)						
	047	64	11	SCREENING						
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	049	90	21	SCREENING	8		0		8	
				V1 (WEEK 0)	12		0		12	
				V3 (WEEK 12)	12	0	0	0	12	0
				V4 (WEEK 24)	12	0	0	0	12	0
				V5 (WEEK 36)	12	0	0	0	12	0
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	051	92	21	SCREENING	7		0		7	
				V1 (WEEK 0)	11		0		11	
				V3 (WEEK 12)	11	0	1	1	12	1
				V4 (WEEK 24)	12	1	0	0	12	1
				V5 (WEEK 36)	12	1	1	1	13	2
				V6 (WEEK 52)	12	1	0	0	12	1
				V7 (WEEK 56)	12	1	0	0	12	1
	056	75	5	SCREENING	9		5		14	
				V1 (WEEK 0)	10		3		13	
				V3 (WEEK 12)						
				V4 (WEEK 24)	11	1	2	-1	13	0

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	049	90	21	SCREENING	12		0		12	
				V1 (WEEK 0)	12		1		13	
				V3 (WEEK 12)	12	0	1	0	13	0
				V4 (WEEK 24)	12	0	1	0	13	0
				V5 (WEEK 36)	12	0	0	-1	12	-1
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	051	92	21	SCREENING	12		1		13	
				V1 (WEEK 0)	12		1		13	
				V3 (WEEK 12)	12	0	1	0	13	0
				V4 (WEEK 24)	12	0	1	0	13	0
				V5 (WEEK 36)	12	0	1	0	13	0
				V6 (WEEK 52)	12	0	1	0	13	0
				V7 (WEEK 56)	12	0	1	0	13	0
	056	75	5	SCREENING	12		4		16	
				V1 (WEEK 0)	12		11		23	
				V3 (WEEK 12)						
				V4 (WEEK 24)	12	0	6	-5	18	-5

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	056	75	5	V5 (WEEK 36)	12	2	4	1	16	3
				V6 (WEEK 52)	12	2	3	0	15	2
				V7 (WEEK 56)	12	2	5	2	17	4
	058	110	1	SCREENING						
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	059	116	1	SCREENING	7		0		7	
				V1 (WEEK 0)	11		0		11	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	056	75	5	V5 (WEEK 36)	12	0	8	-3	20	-3
				V6 (WEEK 52)	12	0	7	-4	19	-4
				V7 (WEEK 56)	12	0	5	-6	17	-6
	058	110	1	SCREENING						
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	059	116	1	SCREENING	11		1		12	
				V1 (WEEK 0)	12		1		13	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	065	84	16	SCREENING	1		0		1	
				V1 (WEEK 0)						
				V3 (WEEK 12)	1		0		1	
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	068	85	16	SCREENING	11		7		18	
				V1 (WEEK 0)	11		6		17	
				V3 (WEEK 12)	12	1	6	0	18	1
				V4 (WEEK 24)	12	1	9	3	21	4
				V5 (WEEK 36)	12	1	7	1	19	2
				V6 (WEEK 52)	10	-1	6	0	16	-1
				V7 (WEEK 56)	12	1	6	0	18	1
	069	100	23	SCREENING	12		2		14	
				V1 (WEEK 0)	12		2		14	
				V3 (WEEK 12)	11	-1	2	0	13	-1
				V4 (WEEK 24)	12	0	6	4	18	4

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	065	84	16	SCREENING	0		0		0	
				V1 (WEEK 0)						
				V3 (WEEK 12)	2		0		2	
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	068	85	16	SCREENING	4		4		8	
				V1 (WEEK 0)	12		10		22	
				V3 (WEEK 12)	12	0	12	2	24	2
				V4 (WEEK 24)						
				V5 (WEEK 36)	4	0	4	1	8	1
				V6 (WEEK 52)	4	0	4	1	8	1
				V7 (WEEK 56)	8	0	6	0	14	0
	069	100	23	SCREENING	12		2		14	
				V1 (WEEK 0)	12		2		14	
				V3 (WEEK 12)	9	-3	4	2	13	-1
				V4 (WEEK 24)	12	0	6	4	18	4

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	069	100	23	V5 (WEEK 36)	12	0	2	0	14	0
				V6 (WEEK 52)	12	0	6	4	18	4
				V7 (WEEK 56)	12	0	9	7	21	7
	072	106	18	SCREENING	5		0		5	
				V1 (WEEK 0)	2		1		3	
				V3 (WEEK 12)	5	3	0	-1	5	2
				V4 (WEEK 24)	9	7	0	-1	9	6
				V5 (WEEK 36)	5	3	0	-1	5	2
				V6 (WEEK 52)	6	4	0	-1	6	3
				V7 (WEEK 56)	8	6	0	-1	8	5
	079	57	13	SCREENING	3		0		3	
				V1 (WEEK 0)	3		0		3	
				V3 (WEEK 12)	8	5	0	0	8	5
				V4 (WEEK 24)	4	1	0	0	4	1
				V5 (WEEK 36)	5	2	0	0	5	2
				V6 (WEEK 52)	6	3	0	0	6	3
				V7 (WEEK 56)	4	1	0	0	4	1

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	069	100	23	V5 (WEEK 36)	12	0	6	4	18	4
				V6 (WEEK 52)	8	0	7	6	15	6
				V7 (WEEK 56)						
	072	106	18	SCREENING	4		1		5	
				V1 (WEEK 0)	9		1		10	
				V3 (WEEK 12)	6	-3	0	-1	6	-4
				V4 (WEEK 24)	10	1	0	-1	10	0
				V5 (WEEK 36)	6	-3	0	-1	6	-4
				V6 (WEEK 52)	4	-5	0	-1	4	-6
				V7 (WEEK 56)	12	3	1	0	13	3
	079	57	13	SCREENING	1		0		1	
				V1 (WEEK 0)	1		0		1	
				V3 (WEEK 12)	9	8	0	0	9	8
				V4 (WEEK 24)	9	8	1	1	10	9
				V5 (WEEK 36)	5	4	0	0	5	4
				V6 (WEEK 52)	8	7	0	0	8	7
				V7 (WEEK 56)	7	6	0	0	7	6

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	082	26	17	SCREENING	9		6		15	
				V1 (WEEK 0)	9		9		18	
				V3 (WEEK 12)	7	-2	9	0	16	-2
				V4 (WEEK 24)	5	-4	9	0	14	-4
				V5 (WEEK 36)	12	3	7	-2	19	1
				V6 (WEEK 52)	8	-1	7	-2	15	-3
				V7 (WEEK 56)	10	1	9	0	19	1
	084	28	17	SCREENING	6		4		10	
				V1 (WEEK 0)	6		6		12	
				V3 (WEEK 12)	7	1	6	0	13	1
				V4 (WEEK 24)	6	0	6	0	12	0
				V5 (WEEK 36)	8	2	4	-2	12	0
				V6 (WEEK 52)	8	2	3	-3	11	-1
				V7 (WEEK 56)	6	0	6	0	12	0
	086	112	21	SCREENING	5		0		5	
				V1 (WEEK 0)	6		0		6	
				V3 (WEEK 12)	8	2	1	1	9	3
				V4 (WEEK 24)	10	4	0	0	10	4

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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Treatment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	082	26	17	SCREENING	10		9		19	
				V1 (WEEK 0)						
				V3 (WEEK 12)	11		12		23	
				V4 (WEEK 24)	11		8		19	
				V5 (WEEK 36)	0		0		0	
				V6 (WEEK 52)	12		9		21	
				V7 (WEEK 56)						
	084	28	17	SCREENING	10		10		20	
				V1 (WEEK 0)	11		7		18	
				V3 (WEEK 12)	12	1	8	1	20	2
				V4 (WEEK 24)	11	0	8	1	19	1
				V5 (WEEK 36)	10	-1	9	2	19	1
				V6 (WEEK 52)	12	1	6	-1	18	0
				V7 (WEEK 56)	12	1	9	2	21	3
	086	112	21	SCREENING	7		1		8	
				V1 (WEEK 0)	4		1		5	
				V3 (WEEK 12)	6	2	1	0	7	2
				V4 (WEEK 24)	10	6	2	1	12	7

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 1-3 (Easy)		PAL Sum Trial 1-3 (Hard)		PAL Sum Trial 1-3 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	086	112	21	V5 (WEEK 36)	12	6	0	0	12	6
				V6 (WEEK 52)	12	6	1	1	13	7
				V7 (WEEK 56)	12	6	3	3	15	9
	088	40	16	SCREENING	0		0		0	
				V1 (WEEK 0)	0		0		0	
				V3 (WEEK 12)	3	3	0	0	3	3
				V4 (WEEK 24)	0	0	0	0	0	0
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

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Listing 16.2.6.8: Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Sum Trial 4-6 (Easy)		PAL Sum Trial 4-6 (Hard)		PAL Sum Trial 4-6 (Total)	
					Derived Value	Difference From Baseline	Derived Value	Difference From Baseline	Derived Value	Difference From Baseline
Placebo	086	112	21	V5 (WEEK 36)	12	8	2	1	14	9
				V6 (WEEK 52)	12	8	1	0	13	8
				V7 (WEEK 56)	12	8	7	6	19	14
	088	40	16	SCREENING						
				V1 (WEEK 0)						
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	002	46	1	SCREENING	4	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	6	0
				V4 (WEEK 24)	5	-1
				V5 (WEEK 36)	2	-4
				V6 (WEEK 52)	2	-4
				V7 (WEEK 56)	1	-5
	004	47	1	SCREENING	2	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	006	8	2	SCREENING	4	
				V1 (WEEK 0)	5	
				V3 (WEEK 12)	4	-1
				V4 (WEEK 24)	3	-2
				V5 (WEEK 36)	4	-1
				V6 (WEEK 52)	3	-2
				V7 (WEEK 56)	4	-1

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	010	10	1	SCREENING	3	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	2	-1
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	012	67	1	SCREENING	1	
				V1 (WEEK 0)	1	
				V3 (WEEK 12)	2	1
				V4 (WEEK 24)	2	1
				V5 (WEEK 36)		
				V6 (WEEK 52)	1	0
				V7 (WEEK 56)		
	014	22	4	SCREENING	5	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	4	1
				V4 (WEEK 24)	4	1
				V5 (WEEK 36)	4	1
				V6 (WEEK 52)	5	2
				V7 (WEEK 56)	4	1

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	015	23	4	SCREENING	2	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	3	0
				V4 (WEEK 24)	3	0
				V5 (WEEK 36)	3	0
				V6 (WEEK 52)	3	0
				V7 (WEEK 56)	4	1
	017	17	5	SCREENING	1	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	1	-1
				V4 (WEEK 24)	1	-1
				V5 (WEEK 36)	3	1
				V6 (WEEK 52)	0	-2
				V7 (WEEK 56)	2	0
	019	19	5	SCREENING	4	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	1	-2
				V4 (WEEK 24)	2	-1
				V5 (WEEK 36)	2	-1
				V6 (WEEK 52)	2	-1
				V7 (WEEK 56)	3	0

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	023	71	4	SCREENING	1	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	2	0
				V4 (WEEK 24)	1	-1
				V5 (WEEK 36)	2	0
				V6 (WEEK 52)	0	-2
				V7 (WEEK 56)	1	-1
	027	87	20	SCREENING	8	
				V1 (WEEK 0)	7	
				V3 (WEEK 12)	5	-2
				V4 (WEEK 24)	7	0
				V5 (WEEK 36)	7	0
				V6 (WEEK 52)	6	-1
				V7 (WEEK 56)	7	0
	030	50	8	SCREENING	4	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	2	-2
				V4 (WEEK 24)	2	-2
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)	0	-4

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	032	52	8	SCREENING	0	
				V1 (WEEK 0)	0	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	033	33	9	SCREENING	6	
				V1 (WEEK 0)	7	
				V3 (WEEK 12)	8	1
				V4 (WEEK 24)	7	0
				V5 (WEEK 36)	6	-1
				V6 (WEEK 52)	8	1
				V7 (WEEK 56)	7	0
	042	70	12	SCREENING	0	
				V1 (WEEK 0)	0	
				V3 (WEEK 12)	2	2
				V4 (WEEK 24)	1	1
				V5 (WEEK 36)	0	0
				V6 (WEEK 52)	0	0
				V7 (WEEK 56)	0	0

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	043	43	12	SCREENING	4	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	3	0
				V4 (WEEK 24)	1	-2
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	046	62	11	SCREENING	1	
				V1 (WEEK 0)		
				V3 (WEEK 12)	2	
				V4 (WEEK 24)	3	
				V5 (WEEK 36)	3	
				V6 (WEEK 52)	2	
				V7 (WEEK 56)	3	
	048	104	11	SCREENING	3	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	5	-1
				V4 (WEEK 24)		
				V5 (WEEK 36)	6	0
				V6 (WEEK 52)	5	-1
				V7 (WEEK 56)	6	0

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	050	93	21	SCREENING	2	
				V1 (WEEK 0)	5	
				V3 (WEEK 12)	5	0
				V4 (WEEK 24)	4	-1
				V5 (WEEK 36)	5	0
				V6 (WEEK 52)	4	-1
				V7 (WEEK 56)	5	0
	052	91	21	SCREENING	0	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	1	-2
				V4 (WEEK 24)	1	-2
				V5 (WEEK 36)	3	0
				V6 (WEEK 52)	4	1
				V7 (WEEK 56)	4	1
	055	76	5	SCREENING	6	
				V1 (WEEK 0)	5	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)	4	-1
				V7 (WEEK 56)		

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	057	68	1	SCREENING	2	
				V1 (WEEK 0)	0	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	066	83	16	SCREENING	4	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	067	38	16	SCREENING	7	
				V1 (WEEK 0)	7	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	071	105	18	SCREENING	1	
				V1 (WEEK 0)	1	
				V3 (WEEK 12)	2	1
				V4 (WEEK 24)	4	3
				V5 (WEEK 36)	3	2
				V6 (WEEK 52)		
				V7 (WEEK 56)	1	0
	080	59	13	SCREENING	4	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	3	-1
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	081	25	17	SCREENING	5	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	7	3
				V4 (WEEK 24)	4	0
				V5 (WEEK 36)	4	0
				V6 (WEEK 52)	0	-4
				V7 (WEEK 56)	1	-3

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	083	27	17	SCREENING	5	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	5	1
				V4 (WEEK 24)	2	-2
				V5 (WEEK 36)	0	-4
				V6 (WEEK 52)	3	-1
				V7 (WEEK 56)	2	-2
	087	39	16	SCREENING	4	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	1	-5
				V4 (WEEK 24)	3	-3
				V5 (WEEK 36)	4	-2
				V6 (WEEK 52)	5	-1
				V7 (WEEK 56)	0	-6
	089	74	5	V3 (WEEK 12)	2	
				SCREENING	2	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	0	-2
				V4 (WEEK 24)		
				V5 (WEEK 36)	0	-2
				V6 (WEEK 52)	0	-2
				V7 (WEEK 56)		

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
ACI-91	093	29	17	SCREENING	0	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	7	3
				V4 (WEEK 24)	5	1
				V5 (WEEK 36)	5	1
				V6 (WEEK 52)	0	-4
				V7 (WEEK 56)	0	-4
	097	69	12	SCREENING	0	
				V1 (WEEK 0)	1	
				V3 (WEEK 12)	0	-1
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
Placebo	001	48	1	SCREENING		
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	2	-1
				V4 (WEEK 24)	3	0
				V5 (WEEK 36)	0	-3
				V6 (WEEK 52)		
				V7 (WEEK 56)	0	-3

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	003	45	1	SCREENING	2	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	005	5	2	SCREENING	6	
				V1 (WEEK 0)	7	
				V3 (WEEK 12)	6	-1
				V4 (WEEK 24)	6	-1
				V5 (WEEK 36)	5	-2
				V6 (WEEK 52)	5	-2
				V7 (WEEK 56)	7	0
	009	11	1	SCREENING	2	
				V1 (WEEK 0)	0	
				V3 (WEEK 12)	3	3
				V4 (WEEK 24)	2	2
				V5 (WEEK 36)	2	2
				V6 (WEEK 52)	2	2
				V7 (WEEK 56)	1	1

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	011	65	1	SCREENING	0	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	1	-1
				V4 (WEEK 24)	1	-1
				V5 (WEEK 36)	1	-1
				V6 (WEEK 52)	0	-2
				V7 (WEEK 56)	0	-2
	013	21	4	SCREENING	2	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	2	0
				V4 (WEEK 24)	2	0
				V5 (WEEK 36)	2	0
				V6 (WEEK 52)	3	1
				V7 (WEEK 56)	3	1
	016	24	4	SCREENING	7	
				V1 (WEEK 0)	7	
				V3 (WEEK 12)	7	0
				V4 (WEEK 24)	7	0
				V5 (WEEK 36)	7	0
				V6 (WEEK 52)	6	-1
				V7 (WEEK 56)	4	-3

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	018	18	5	SCREENING	2	
				V1 (WEEK 0)	0	
				V3 (WEEK 12)	0	0
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	020	20	5	SCREENING	1	
				V1 (WEEK 0)		
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	024	72	4	SCREENING	2	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	2	-2
				V4 (WEEK 24)	3	-1
				V5 (WEEK 36)	4	0
				V6 (WEEK 52)	4	0
				V7 (WEEK 56)	5	1

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	028	88	20	SCREENING	0	
				V1 (WEEK 0)	0	
				V3 (WEEK 12)	0	0
				V4 (WEEK 24)	0	0
				V5 (WEEK 36)	0	0
				V6 (WEEK 52)	0	0
				V7 (WEEK 56)	0	0
	029	49	8	SCREENING	6	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	5	-1
				V4 (WEEK 24)	6	0
				V5 (WEEK 36)	7	1
				V6 (WEEK 52)	7	1
				V7 (WEEK 56)	8	2
	031	51	8	SCREENING	1	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	3	0
				V4 (WEEK 24)	2	-1
				V5 (WEEK 36)	0	-3
				V6 (WEEK 52)	2	-1
				V7 (WEEK 56)	2	-1

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	034	34	9	SCREENING		
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	3	0
				V4 (WEEK 24)	2	-1
				V5 (WEEK 36)	1	-2
				V6 (WEEK 52)	1	-2
				V7 (WEEK 56)	3	0
	041	41	12	SCREENING	1	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	0	-2
				V4 (WEEK 24)	2	0
				V5 (WEEK 36)	1	-1
				V6 (WEEK 52)	0	-2
				V7 (WEEK 56)	3	1
	044	44	12	SCREENING	2	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	2	0
				V4 (WEEK 24)	2	0
				V5 (WEEK 36)	3	1
				V6 (WEEK 52)	2	0
				V7 (WEEK 56)	1	-1

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	045	61	11	SCREENING	7	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	6	0
				V4 (WEEK 24)	3	-3
				V5 (WEEK 36)	8	2
				V6 (WEEK 52)	0	-6
				V7 (WEEK 56)	7	1
	047	64	11	SCREENING		
				V1 (WEEK 0)		
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	049	90	21	SCREENING	4	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	4	2
				V4 (WEEK 24)	4	2
				V5 (WEEK 36)	4	2
				V6 (WEEK 52)		
				V7 (WEEK 56)		

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	051	92	21	SCREENING	3	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	4	0
				V4 (WEEK 24)	4	0
				V5 (WEEK 36)	4	0
				V6 (WEEK 52)	4	0
				V7 (WEEK 56)	4	0
	056	75	5	SCREENING	4	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)		
				V4 (WEEK 24)	5	1
				V5 (WEEK 36)	7	3
				V6 (WEEK 52)	4	0
				V7 (WEEK 56)	4	0
	058	110	1	SCREENING		
				V1 (WEEK 0)		
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	059	116	1	SCREENING	2	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	065	84	16	SCREENING		
				V1 (WEEK 0)		
				V3 (WEEK 12)	1	
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		
	068	85	16	SCREENING	8	
				V1 (WEEK 0)	8	
				V3 (WEEK 12)	8	0
				V4 (WEEK 24)	7	-1
				V5 (WEEK 36)	7	-1
				V6 (WEEK 52)	8	0
				V7 (WEEK 56)	7	-1

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	069	100	23	SCREENING	4	
				V1 (WEEK 0)	4	
				V3 (WEEK 12)	4	0
				V4 (WEEK 24)	5	1
				V5 (WEEK 36)	4	0
				V6 (WEEK 52)	7	3
				V7 (WEEK 56)	7	3
	072	106	18	SCREENING	3	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	1	-2
				V4 (WEEK 24)	0	-3
				V5 (WEEK 36)	2	-1
				V6 (WEEK 52)	1	-2
				V7 (WEEK 56)	1	-2
	079	57	13	SCREENING	0	
				V1 (WEEK 0)	0	
				V3 (WEEK 12)	2	2
				V4 (WEEK 24)	1	1
				V5 (WEEK 36)	1	1
				V6 (WEEK 52)	2	2
				V7 (WEEK 56)	0	0

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	082	26	17	SCREENING	6	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	6	0
				V4 (WEEK 24)	4	-2
				V5 (WEEK 36)	6	0
				V6 (WEEK 52)	5	-1
				V7 (WEEK 56)	4	-2
	084	28	17	SCREENING	2	
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	6	3
				V4 (WEEK 24)	3	0
				V5 (WEEK 36)	3	0
				V6 (WEEK 52)	2	-1
				V7 (WEEK 56)	2	-1
	086	112	21	SCREENING	2	
				V1 (WEEK 0)	2	
				V3 (WEEK 12)	2	0
				V4 (WEEK 24)	3	1
				V5 (WEEK 36)	5	3
				V6 (WEEK 52)	5	3
				V7 (WEEK 56)	4	2

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Listing 16.2.6.9: Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	PAL Delayed Trial (Sum Easy/Hard)	Difference From Baseline
Placebo	088	40	16	SCREENING		
				V1 (WEEK 0)		
				V3 (WEEK 12)		
				V4 (WEEK 24)		
				V5 (WEEK 36)		
				V6 (WEEK 52)		
				V7 (WEEK 56)		

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	002	46	1	SCREENING	9		17		4	
				V1 (WEEK 0)	12		21		6	
				V3 (WEEK 12)	13	1	21	0	7	
				V4 (WEEK 24)	12	0	21	0	7	
				V5 (WEEK 36)	12	0	20	-1	6	
				V6 (WEEK 52)	18	6	28	7	7	1
				V7 (WEEK 56)	15	3	24	3	7	
	004	47	1	SCREENING	9		16		5	
				V1 (WEEK 0)	12		20		5	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	006	8	2	SCREENING	9		17		6	
				V1 (WEEK 0)	13		22		5	1
				V3 (WEEK 12)	23	10	33	11	7	1
				V4 (WEEK 24)	25	12	34	12	7	1
				V5 (WEEK 36)	17	4	27	5	7	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	002	46	1	0	8	0		2	
				0	9	0		2	
				0	8	0		1	
				0	9	0		1	
				0	8	0	1		
				0	10	0		3	
				0	9	0		4	
	004	47	1	1	7	0			
				0	8	0		3	
	006	8	2	0	8	0		1	
				0	9	0			
				0	10	0		1	
				0	9	0		1	
				1	10	0	1	1	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	002	46	1	3	0	0	0	0
				4	0	0	0	0
				5	0	0	0	0
				4	0	0	0	0
				3	1	0	1	0
				7	0	0	0	0
				4	0	0	0	0
	004	47	1	2	0	0	1	0
				3	0	0	1	0
	006	8	2	2	0	0	0	0
				6	0	0	1	0
				8	0	2	2	2
				6	4	2	2	2
				4	0	1	1	1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	006	8	2	V6 (WEEK 52)	26	13	36	14	7	2
				V7 (WEEK 56)	30	17	40	18	7	
	010	10	1	SCREENING	11		17		5	
				V1 (WEEK 0)	15		24		7	
				V3 (WEEK 12)	17	2	26	2	7	
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	012	67	1	SCREENING	18		25		6	
				V1 (WEEK 0)	16		24		6	
				V3 (WEEK 12)	16	0	25	1	6	
				V4 (WEEK 24)	25	9	33	9	7	
				V5 (WEEK 36)	19	3	27	3	7	
				V6 (WEEK 52)	15	-1	25	1	8	
				V7 (WEEK 56)	25	9	35	11	6	
	014	22	4	SCREENING	15		22		6	
				V1 (WEEK 0)	14		23		7	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	006	8	2	0	10	0	1	5	
				1	10	0		2	
	010	10	1	0	6	0		2	
				0	9	0		4	
				0	9	0	1	3	
	012	67	1	0	7	0		1	
				0	8	0	1	1	
				0	9	0		1	
				0	8	1	1	1	
				0	8	0		1	
				0	10	0		1	
				0	10	0	1	3	
	014	22	4	0	7	1		1	
				0	9	0		1	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	006	8	2	6	0	1	2	2
				11	3	2	2	2
	010	10	1	3	0	0	1	0
				4	0	0	0	0
				4	0	0	1	1
	012	67	1	9	0	1	1	0
				6	0	1	1	0
				8	0	0	1	0
				9	0	1	2	1
				9	0	0	1	1
				4	0	1	1	0
				9	0	2	2	2
	014	22	4	2	3	0	2	0
				2	1	0	1	1

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	014	22	4	V3 (WEEK 12)	9	-5	16	-7	5	
				V4 (WEEK 24)	17	3	26	3	7	1
				V5 (WEEK 36)	19	5	27	4	8	1
				V6 (WEEK 52)	12	-2	22	-1	6	
				V7 (WEEK 56)	13	-1	21	-2	7	
	015	23	4	SCREENING	20		30		7	
				V1 (WEEK 0)	22		31		7	
				V3 (WEEK 12)	20	-2	29	-2	7	
				V4 (WEEK 24)	23	1	33	2	8	1
				V5 (WEEK 36)	24	2	34	3	7	1
				V6 (WEEK 52)	30	8	40	9	8	2
				V7 (WEEK 56)	21	-1	31	0	7	
	017	17	5	SCREENING	16		25		6	
				V1 (WEEK 0)	15		25		5	
				V3 (WEEK 12)	20	5	30	5	6	
				V4 (WEEK 24)	22	7	32	7	8	
				V5 (WEEK 36)	21	6	31	6	6	
				V6 (WEEK 52)	24	9	34	9	7	
				V7 (WEEK 56)	20	5	30	5	7	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	014	22	4	0	7	0		1	
				0	9	0		2	
				0	8	0		4	
				0	10	0		2	
				0	8	0		4	
	015	23	4	0	10	0		5	
				0	9	0		5	
				0	9	0		4	
				0	10	0		4	
				0	10	0		4	
				1	10	0	1	7	
				0	10	0		4	
	017	17	5	0	9	0	1	1	
				0	10	0	1	2	
				0	10	0		4	
				0	10	0	1	3	
				0	10	0		5	
				0	10	0	1	6	
				0	10	0		4	
				0	10	0		4	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	014	22	4	1	1	0	1	0
				3	2	0	2	0
				4	0	1	1	0
				2	0	1	1	0
				1	0	0	1	0
	015	23	4	5	3	0	0	0
				8	2	0	0	0
				7	2	0	0	0
				8	2	0	0	0
				8	3	0	1	0
				8	1	0	1	1
				6	2	0	1	1
	017	17	5	8	0	0	0	0
				6	1	0	0	0
				7	2	0	1	0
				7	0	1	1	1
				7	2	0	1	0
				6	1	1	1	1
				6	0	1	2	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	019	19	5	SCREENING	14		23		3	1
				V1 (WEEK 0)	12		22		5	
				V3 (WEEK 12)	21	9	31	9	6	
				V4 (WEEK 24)	19	7	29	7	6	2
				V5 (WEEK 36)	23	11	33	11	6	1
				V6 (WEEK 52)	16	4	26	4	5	1
				V7 (WEEK 56)	15	3	25	3	5	1
	023	71	4	SCREENING	20		29		7	1
				V1 (WEEK 0)	17		27		7	1
				V3 (WEEK 12)	37	20	47	20	9	3
				V4 (WEEK 24)	35	18	45	18	9	3
				V5 (WEEK 36)	37	20	47	20	9	3
				V6 (WEEK 52)	49	32	59	32	10	4
				V7 (WEEK 56)	52	35	62	35	9	4
	027	87	20	SCREENING	11		16		4	1
				V1 (WEEK 0)	16		21		4	2
				V3 (WEEK 12)	13	-3	22	1	5	1
				V4 (WEEK 24)	11	-5	20	-1	6	
				V5 (WEEK 36)	15	-1	22	1	4	1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	019	19	5	0	9	0		4	
				0	10	0		2	
				0	10	0		6	
				0	10	0		3	
				1	10	0		4	
				0	10	0		3	
				0	10	0		2	
	023	71	4	1	9	1		1	
				1	10	0		1	
				1	10	1	1	6	
				1	10	0	1	5	
				0	10	1	1	5	
				2	10	3	2	6	
				1	10	2	5	6	
	027	87	20	0	5	0		1	
				0	5	0		1	
				0	9	1		2	
				0	9	0		2	
				1	7	0		3	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	019	19	5	1	3	0	1	1
				4	0	0	1	0
				6	0	0	1	2
				6	0	0	1	1
				7	1	0	1	2
				5	0	0	1	1
				5	0	0	1	1
	023	71	4	5	3	0	1	0
				4	2	0	1	0
				4	5	2	2	3
				4	5	2	2	3
				6	5	2	2	3
				10	5	2	2	3
				12	5	2	3	3
	027	87	20	0	3	1	1	0
				5	2	1	1	0
				2	2	0	0	0
				2	0	0	1	0
				2	0	2	1	1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	027	87	20	V6 (WEEK 52)	15	-1	22	1	4	
				V7 (WEEK 56)	12	-4	19	-2	4	
	030	50	8	SCREENING	20		28		6	1
				V1 (WEEK 0)	19		28		6	1
				V3 (WEEK 12)	26	7	36	8	8	1
				V4 (WEEK 24)	33	14	43	15	7	1
				V5 (WEEK 36)	30	11	40	12	8	3
				V6 (WEEK 52)	43	24	53	25	9	2
				V7 (WEEK 56)	31	12	41	13	8	1
	032	52	8	SCREENING	17		27		6	1
				V1 (WEEK 0)	14		24		5	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	033	33	9	SCREENING	9		10		3	1
				V1 (WEEK 0)	11		14		4	1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1= TU München, 2= UK Ulm, 4= LMU München, 5= Charite Berlin, 8= UK Aachen, 9= Magdeburg, 11= UK Tübingen, 12= Elmshorn, 13= Bochum
16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	027	87	20	0	7	0	1	4	
				1	7	0		2	
	030	50	8	3	8	0		3	
				3	9	1		1	
				5	10	2		4	
				5	10	1	4	4	
				3	10	1	1	3	
				3	10	1	2	5	
				3	10	2	3	5	
	032	52	8	1	10	0		2	
				1	10	0		1	
	033	33	9	2	1	0	1	1	
				3	3	0		1	

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1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	027	87	20	3	1	1	1	0
				2	0	1	1	1
	030	50	8	6	0	0	1	0
				6	0	0	1	0
				4	0	0	1	1
				8	1	0	1	1
				8	0	1	1	1
				10	5	1	2	3
				5	0	1	2	1
	032	52	8	7	0	0	0	0
				7	0	0	0	0
	033	33	9	1	0	0	0	0
				1	0	0	0	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	033	33	9	V3 (WEEK 12)	9	-2	14	0	5	
				V4 (WEEK 24)	9	-2	13	-1	4	1
				V5 (WEEK 36)	17	6	21	7	6	2
				V6 (WEEK 52)	18	7	25	11	5	
				V7 (WEEK 56)	10	-1	15	1	5	
	042	70	12	SCREENING	23		33		5	3
				V1 (WEEK 0)	26		36		5	2
				V3 (WEEK 12)	37	11	47	11	7	3
				V4 (WEEK 24)	39	13	49	13	7	4
				V5 (WEEK 36)	45	19	55	19	6	4
				V6 (WEEK 52)	40	14	50	14	8	3
				V7 (WEEK 56)	41	15	51	15	6	4
	043	43	12	SCREENING	17		23		6	1
				V1 (WEEK 0)	15		25		6	1
				V3 (WEEK 12)	17	2	24	-1	6	1
				V4 (WEEK 24)	46	31	55	30	9	2
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score
ACI-91	033	33	9	2	5	0		1
				2	4	0		1
				2	4	0		1
				2	7	0	1	2
				3	5	0		
	042	70	12	2	10	0		3
				2	10	0		4
				2	10	0	1	5
				1	10	0	2	6
				3	10	0	3	5
				2	10	0	2	5
				2	10	0	1	7
	043	43	12	1	6	0		
				0	10	0	1	3
				0	7	0		2
				5	9	1	5	3

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	033	33	9	1	0	0	0	0
				1	0	0	0	0
				0	2	1	1	2
				5	3	0	0	0
				1	1	0	0	0
	042	70	12	6	3	0	0	1
				7	5	0	1	0
				9	5	1	1	3
				9	5	1	1	3
				11	5	2	3	3
				9	5	1	2	3
				11	5	2	1	2
	043	43	12	3	4	0	0	2
				2	1	0	0	1
				3	3	1	0	1
				9	4	2	3	3

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	046	62	11	SCREENING	27		37		6	1
				V1 (WEEK 0)	22		32		7	
				V3 (WEEK 12)	25	3	34	2	7	
				V4 (WEEK 24)	28	6	38	6	8	1
				V5 (WEEK 36)	28	6	38	6	6	
				V6 (WEEK 52)	25	3	35	3	8	
				V7 (WEEK 56)	28	6	38	6	7	
	048	104	11	SCREENING	12		20		5	
				V1 (WEEK 0)	18		28		6	
				V3 (WEEK 12)	16	-2	25	-3	5	
				V4 (WEEK 24)	11	-7	18	-10	6	
				V5 (WEEK 36)	18	0	26	-2	6	
				V6 (WEEK 52)	20	2	30	2	7	
				V7 (WEEK 56)	21	3	31	3	6	
	050	93	21	SCREENING	20		29		7	1
				V1 (WEEK 0)	18		27		6	1
				V3 (WEEK 12)	23	5	33	6	7	1
				V4 (WEEK 24)	21	3	31	4	8	1
				V5 (WEEK 36)	17	-1	27	0	7	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	046	62	11	0	10	0	1	5	
				1	10	0		7	
				1	9	1	1	6	
				1	10	1		6	
				1	10	1	1	6	
				1	10	1	1	5	
				2	10	0	2	6	
	048	104	11	1	8	0		4	
				0	10	0		4	
				0	9	0	1	5	
				0	7	0		2	
				0	8	0	1	4	
				1	10	0	1	5	
				1	10	0	1	6	
	050	93	21	1	9	0		3	
				1	9	0	1	3	
				1	10	0		5	
				1	10	0		4	
				2	10	0		4	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	046	62	11	8	4	0	1	1
				5	0	1	1	0
				7	0	1	1	0
				7	3	1	0	0
				7	3	0	1	2
				6	0	1	1	1
				7	1	1	1	1
	048	104	11	2	0	0	0	0
				5	1	1	1	0
				3	0	0	1	1
				1	1	0	0	1
				4	0	1	1	1
				5	0	0	1	0
				4	0	1	1	1
	050	93	21	7	0	0	0	1
				6	0	0	0	0
				6	3	0	0	0
				5	2	0	0	0
				3	0	0	0	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	050	93	21	V6 (WEEK 52)	28	10	36	9	8	3
				V7 (WEEK 56)	16	-2	25	-2	6	1
	052	91	21	SCREENING	19		29		7	
				V1 (WEEK 0)	20		30		7	2
				V3 (WEEK 12)	27	7	37	7	8	1
				V4 (WEEK 24)	20	0	30	0	8	1
				V5 (WEEK 36)	25	5	35	5	8	1
				V6 (WEEK 52)	26	6	36	6	8	2
				V7 (WEEK 56)	20	0	30	0	7	2
	055	76	5	SCREENING	15		25		5	
				V1 (WEEK 0)	18		27		5	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)	16	-2	25	-2	6	
				V7 (WEEK 56)						
	057	68	1	SCREENING	15		20		5	2
				V1 (WEEK 0)	19		25		7	2

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	050	93	21	2	8	0		5	
				1	9	0		3	
	052	91	21	0	10	0	1	5	
				1	10	0		2	
				1	10	0	1	6	
				1	10	0		5	
				2	10	0	1	5	
				2	10	0	1	4	
				1	10	0		4	
	055	76	5	1	10	0		4	
				2	9	1		2	
	057	68	1	1	5	2		2	
				1	6	1	2	2	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	050	93	21	7	2	0	1	0
				4	1	0	0	0
	052	91	21	5	0	0	1	0
				7	0	0	1	0
				7	2	0	1	0
				4	1	0	0	0
				7	0	0	1	0
				8	0	0	1	0
				5	0	0	1	0
				3	0	0	1	1
				6	0	1	1	0
				6	0	0	1	0
	057	68	1	0	0	1	1	1
				1	0	1	1	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	057	68	1	V3 (WEEK 12)	21	2	28	3	6	3
				V4 (WEEK 24)	25	6	33	8	8	3
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	066	83	16	SCREENING	27		35		6	2
				V1 (WEEK 0)	31		38		9	2
				V3 (WEEK 12)	45	14	55	17	8	3
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	067	38	16	SCREENING	12		18		5	
				V1 (WEEK 0)	9		13		3	
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	057	68	1	1	7	2		4	
				2	8	2	1	4	
	066	83	16	1	8	0	2	3	
				0	7	0	3	4	
				2	10	1	5	7	
	067	38	16	0	6	0		1	
				0	4	0			

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	057	68	1	2	0	1	1	1
				0	0	2	2	1
	066	83	16	3	4	1	2	3
				5	4	0	1	3
				5	5	3	3	3
	067	38	16	1	2	1	1	1
				0	2	2	1	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	071	105	18	SCREENING	19		27		6	
				V1 (WEEK 0)	15		23		6	
				V3 (WEEK 12)	22	7	31	8	7	
				V4 (WEEK 24)	22	7	32	9	7	
				V5 (WEEK 36)	31	16	40	17	8	
				V6 (WEEK 52)	30	15	40	17	7	2
				V7 (WEEK 56)	22	7	31	8	7	
	080	59	13	SCREENING	13		23		6	1
				V1 (WEEK 0)	15		25		6	
				V3 (WEEK 12)	25	10	34	9	7	
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	081	25	17	SCREENING	19		27		5	2
				V1 (WEEK 0)	23		33		6	1
				V3 (WEEK 12)	23	0	33	0	6	1
				V4 (WEEK 24)	28	5	38	5	7	3
				V5 (WEEK 36)	26	3	35	2	7	2

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	071	105	18	1	8	0		2	
				1	8	1		2	
				2	9	1	2	4	
				3	10	1	2	3	
				2	9	0	1	7	
				1	10	3	1	5	
				1	9	2	1	5	
	080	59	13	1	10	0	2	1	
				1	10	0		1	
				1	9	0	4	5	
	081	25	17	1	8	0	2	3	
				1	10	1	2	3	
				1	10	1	2	2	
				3	10	1	2	3	
				1	9	1	3	3	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	071	105	18	8	0	1	1	0
				5	0	0	0	0
				5	0	0	0	1
				5	0	1	0	0
				10	0	1	1	1
				7	3	0	0	1
				4	2	0	0	0
	080	59	13	2	0	0	0	0
				7	0	0	0	0
				8	0	0	0	0
	081	25	17	6	0	0	0	0
				8	0	0	1	0
				10	0	0	0	0
				8	0	0	1	0
				7	2	0	0	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	081	25	17	V6 (WEEK 52)	45	22	55	22	9	3
				V7 (WEEK 56)	36	13	46	13	8	2
	083	27	17	SCREENING	23		33		6	1
				V1 (WEEK 0)	24		34		6	2
				V3 (WEEK 12)	28	4	37	3	7	1
				V4 (WEEK 24)	27	3	37	3	6	1
				V5 (WEEK 36)	37	13	47	13	8	2
				V6 (WEEK 52)	19	-5	28	-6	5	1
				V7 (WEEK 56)	21	-3	30	-4	7	1
	087	39	16	SCREENING	17		25		4	
				V1 (WEEK 0)	8		16		5	1
				V3 (WEEK 12)	31	23	41	25	7	2
				V4 (WEEK 24)	28	20	38	22	7	
				V5 (WEEK 36)	44	36	54	38	8	3
				V6 (WEEK 52)	26	18	36	20	5	1
				V7 (WEEK 56)	37	29	47	31	9	1
				V3 (WEEK 12)	29		38		8	2
	089	74	5	SCREENING	34		43		6	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	081	25	17	3	10	2	4	4	
				3	10	1	3	3	
	083	27	17	2	10	1	2	2	
				2	10	1	3	3	
				3	9	1	3	3	
				2	10	1	2	3	
				3	10	2	2	3	
				2	9	1	1	3	
				2	9	0	1	3	
	087	39	16	0	8	0	2	2	
				0	8	0		1	
				0	10	0	1	5	
				1	10	0	1	6	
				2	10	0		7	
				0	10	0		5	
				1	10	0		7	
				0	9	0	3	2	
	089	74	5	2	9	0		1	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	081	25	17	10	5	2	2	1
				6	5	2	1	2
	083	27	17	7	1	0	1	0
				7	0	0	0	0
				8	1	0	0	1
				8	1	1	1	1
				9	4	1	2	1
				5	1	0	0	0
				7	0	0	0	0
	087	39	16	4	3	0	0	2
				1	0	0	0	0
				8	5	0	1	2
				6	5	0	1	1
				12	4	3	2	3
				7	4	0	2	2
				6	5	3	2	3
				7	5	0	0	2
	089	74	5	12	3	3	3	3

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	089	74	5	V1 (WEEK 0)	35		45		7	2
				V3 (WEEK 12)	30	-5	40	-5	8	2
				V4 (WEEK 24)	44	9	54	9	9	2
				V5 (WEEK 36)	41	6	51	6	8	2
				V6 (WEEK 52)	61	26	71	26	10	4
				V7 (WEEK 56)	56	21	66	21	10	4
	093	29	17	SCREENING	30		40		7	2
				V1 (WEEK 0)	23		33		7	1
				V3 (WEEK 12)	21	-2	30	-3	7	1
				V4 (WEEK 24)	26	3	36	3	6	1
				V5 (WEEK 36)	37	14	47	14	8	2
				V6 (WEEK 52)	38	15	48	15	7	3
				V7 (WEEK 56)	40	17	50	17	8	3
	097	69	12	SCREENING	32		42		8	3
				V1 (WEEK 0)	36		46		8	2
				V3 (WEEK 12)	42	6	52	6	8	3
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

1= TU München, 2= UK Ulm, 4= LMU München, 5= Charite Berlin, 8= UK Aachen, 9= Magdeburg, 11= UK Tübingen, 12= Elmshorn, 13= Bochum
16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	089	74	5	1	10	0		1	
				1	10	0	1		
				2	10	1	3	1	
				2	10	1	2	4	
				3	10	2	4	6	
				2	10	2	3	5	
	093	29	17	3	10	2	2	3	
				2	10	1	2	2	
				1	9	1	2	2	
				2	10	1	2	3	
				3	10	2	3	3	
				3	10	2	3	4	
				3	10	2	3	4	
	097	69	12	2	10	2	2	3	
				3	10	2	3	1	
				3	10	2	2	5	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	089	74	5	12	5	2	3	2
				10	5	1	1	1
				12	5	3	4	2
				12	3	2	3	2
				12	5	5	5	5
				12	5	5	5	3
	093	29	17	7	2	1	1	0
				8	0	0	0	0
				6	0	0	0	1
				8	1	1	0	1
				10	3	1	1	1
				9	3	2	1	1
				9	2	2	2	2
	097	69	12	5	2	1	2	2
				10	4	0	1	2
				11	5	1	1	1

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
ACI-91	097	69	12	V7 (WEEK 56)						
Placebo	001	48	1	SCREENING	18		28		7	1
				V1 (WEEK 0)	27		36		8	1
				V3 (WEEK 12)	29	2	39	3	8	1
				V4 (WEEK 24)	30	3	40	4	9	2
				V5 (WEEK 36)	32	5	42	6	8	1
				V6 (WEEK 52)	36	9	46	10	9	2
				V7 (WEEK 56)	45	18	55	19	8	2
	003	45	1	SCREENING	14		21		7	2
				V1 (WEEK 0)	15		23		7	1
				V3 (WEEK 12)	19	4	27	4	6	2
				V4 (WEEK 24)	30	15	39	16	6	3
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	005	5	2	SCREENING	9		16		4	
				V1 (WEEK 0)	13		19		4	1
				V3 (WEEK 12)	12	-1	20	1	4	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
ACI-91	097	69	12						
Placebo	001	48	1	1	10	0			3
				1	9	0		4	
				1	10	0		5	
				1	10	0		5	
				1	10	1	1	5	
				1	10	0	1	7	
				1	10	2	1	7	
	003	45	1	1	7	1			2
				0	8	0		2	
				1	8	1	1	4	
				0	9	1		5	
	005	5	2	0	7	0			2
				1	6	0	1	2	
				1	8	0	1	3	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
ACI-91	097	69	12					
Placebo	001	48	1	5	0	0	1	0
				11	1	0	1	0
				10	3	0	1	0
				11	1	0	1	0
				10	2	1	1	1
				11	4	0	0	1
				12	5	2	1	4
	003	45	1	0	0	0	1	0
				4	0	0	1	0
				3	0	0	1	0
				11	2	0	1	1
	005	5	2	2	0	0	1	0
				3	0	0	1	0
				2	0	0	1	0

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	005	5	2	V4 (WEEK 24)	14	1	22	3	6	
				V5 (WEEK 36)	13	0	20	1	4	1
				V6 (WEEK 52)	17	4	27	8	5	1
				V7 (WEEK 56)	16	3	25	6	5	
	009	11	1	SCREENING	18		28		6	2
				V1 (WEEK 0)	24		34		6	1
				V3 (WEEK 12)	19	-5	29	-5	7	
				V4 (WEEK 24)	21	-3	31	-3	7	2
				V5 (WEEK 36)	18	-6	28	-6	6	1
				V6 (WEEK 52)	19	-5	29	-5	6	
				V7 (WEEK 56)	22	-2	32	-2	8	
	011	65	1	SCREENING	11		21		6	1
				V1 (WEEK 0)	19		27		7	2
				V3 (WEEK 12)	18	-1	28	1	7	1
				V4 (WEEK 24)	28	9	38	11	8	1
				V5 (WEEK 36)	21	2	29	2	8	1
				V6 (WEEK 52)	33	14	43	16	8	2
				V7 (WEEK 56)	26	7	35	8	7	2

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	005	5	2	1	8	1	1		
				1	7	0	1		
				1	10	0		2	
				1	9	0		5	
	009	11	1	1	10	0		4	
				1	10	0		4	
				1	10	0		5	
				1	10	0		3	
				1	10	0		5	
				1	10	1		6	
				1	10	0	2	6	
	011	65	1	0	10	0		2	
				0	8	0		2	
				0	10	0	1	5	
				0	10	1	1	6	
				0	8	0	1	5	
				0	10	0	1	6	
				0	9	0		3	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	005	5	2	4	0	0	1	0
				4	0	0	1	1
				6	0	0	1	1
				2	0	1	1	1
	009	11	1	4	1	0	0	0
				8	3	0	1	0
				6	0	0	0	0
				7	0	0	1	0
				4	0	0	1	0
				3	0	0	2	0
				3	1	0	1	0
	011	65	1	2	0	0	0	0
				4	1	1	1	1
				3	0	0	1	0
				9	0	1	1	0
				5	0	0	1	0
				8	4	0	2	2
				7	2	2	2	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	013	21	4	SCREENING	26		36		6	
				V1 (WEEK 0)	20		30		5	
				V3 (WEEK 12)	19	-1	29	-1	7	
				V4 (WEEK 24)	22	2	32	2	6	
				V5 (WEEK 36)	20	0	30	0	7	
				V6 (WEEK 52)	16	-4	26	-4	6	
				V7 (WEEK 56)	20	0	30	0	7	
	016	24	4	SCREENING	11		19		5	1
				V1 (WEEK 0)	13		21		5	1
				V3 (WEEK 12)	13	0	23	2	6	1
				V4 (WEEK 24)	9	-4	18	-3	5	
				V5 (WEEK 36)	9	-4	18	-3	5	
				V6 (WEEK 52)	21	8	31	10	8	1
				V7 (WEEK 56)	18	5	28	7	6	1
	018	18	5	SCREENING	37		47		8	2
				V1 (WEEK 0)	38		48		8	2
				V3 (WEEK 12)	48	10	58	10	9	2
				V4 (WEEK 24)	47	9	57	9	9	3
				V5 (WEEK 36)	48	10	58	10	9	2

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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				Derived Scores				
Treat- ment	Random No.	CRF Book No.	Site ID	Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score
Placebo	013	21	4	0	10	0	1	7
				0	10	0	1	6
				0	10	0	1	5
				0	10	0	1	6
				0	10	0	1	5
				0	10	0	1	3
				0	10	0	1	4
	016	24	4	0	8	0		
				0	8	0		2
				0	10	0		2
				0	9	0		
				0	9	0		1
				0	10	0	1	2
				0	10	0	1	
	018	18	5	1	10	1	1	5
				1	10	2	3	4
				1	10	3	2	5
				2	10	3	1	5
				1	10	3	1	6

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	013	21	4	7	3	0	1	1
				7	1	0	0	0
				5	1	0	0	0
				6	2	0	1	0
				5	2	0	0	0
				4	2	0	0	0
				5	3	0	0	0
	016	24	4	4	0	0	1	0
				4	0	0	1	0
				4	0	0	0	0
				3	0	0	1	0
				3	0	0	0	0
				9	0	0	0	0
				8	1	0	0	1
	018	18	5	9	3	2	3	2
				7	4	2	3	2
				12	5	3	3	3
				12	4	2	3	3
				12	5	3	3	3

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	018	18	5	V6 (WEEK 52)	45	7	55	7	9	3
				V7 (WEEK 56)	49	11	59	11	8	3
	020	20	5	SCREENING	39		49		9	2
				V1 (WEEK 0)	47		57		9	2
				V3 (WEEK 12)						
				V4 (WEEK 24)						
				V5 (WEEK 36)						
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	024	72	4	SCREENING	19		29		7	
				V1 (WEEK 0)	22		32		7	1
				V3 (WEEK 12)	20	-2	30	-2	7	1
				V4 (WEEK 24)	23	1	33	1	7	1
				V5 (WEEK 36)	19	-3	29	-3	6	1
				V6 (WEEK 52)	23	1	32	0	7	1
				V7 (WEEK 56)	20	-2	30	-2	7	
	028	88	20	SCREENING	23		33		7	5
				V1 (WEEK 0)	19		29		7	2

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	018	18	5	1	10	4	1	6	
				1	10	3	1	7	
	020	20	5	3	10	0	1	3	
				3	10	1	1	6	
	024	72	4	1	10	0		5	
				1	10	0	1	5	
				1	10	0	2	5	
				2	10	0	4	4	
				2	10	0	1	6	
				1	9	0	2	6	
				2	10	0	2	4	
	028	88	20	0	10	4		1	
				1	10	3			

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	018	18	5	8	3	3	4	3
				10	5	4	4	3
	020	20	5	10	5	2	2	2
				10	5	4	3	3
	024	72	4	4	1	0	1	0
				3	0	1	2	1
				2	0	1	1	0
				3	0	0	1	1
				3	0	0	0	0
				4	1	0	1	0
				4	1	0	0	0
	028	88	20	5	0	0	0	1
				5	0	0	1	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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13FEB2013

Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	028	88	20	V3 (WEEK 12)	21	2	30	1	6	3
				V4 (WEEK 24)	21	2	31	2	8	3
				V5 (WEEK 36)	34	15	44	15	7	5
				V6 (WEEK 52)	33	14	43	14	7	5
				V7 (WEEK 56)	35	16	45	16	7	5
	029	49	8	SCREENING	13		22		5	1
				V1 (WEEK 0)	13		20		5	1
				V3 (WEEK 12)	8	-5	14	-6	4	1
				V4 (WEEK 24)	15	2	23	3	6	2
				V5 (WEEK 36)	13	0	19	-1	6	1
				V6 (WEEK 52)	17	4	25	5	7	1
				V7 (WEEK 56)	9	-4	16	-4	5	
	031	51	8	SCREENING	15		23		6	1
				V1 (WEEK 0)	12		21		6	
				V3 (WEEK 12)	8	-4	16	-5	4	
				V4 (WEEK 24)	7	-5	17	-4	5	
				V5 (WEEK 36)	12	0	18	-3	4	
				V6 (WEEK 52)	14	2	23	2	6	1
				V7 (WEEK 56)	13	1	19	-2	5	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	028	88	20	0	9	3	1	1	
				0	10	3	1		
				0	10	4	1	1	
				0	10	5		2	
				0	10	4	1	3	
	029	49	8	1	9	0		3	
				1	7	0	1	2	
				1	6	0		1	
				1	8	0		1	
				2	6	0		1	
				1	8	0		2	
				1	7	0		1	
	031	51	8	1	8	0		4	
				1	9	0			
				0	8	0		1	
				1	10	0			
				1	6	0		3	
				1	9	0		1	
				1	6	0		1	

Random no. 87 with book no. 54 on visit 3 is excluded from analysis

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	028	88	20	6	0	0	1	0
				5	0	1	0	0
				10	3	1	1	1
				4	3	1	3	3
				10	3	1	1	0
	029	49	8	3	0	0	0	0
				3	0	0	0	0
				1	0	0	0	0
				2	1	0	1	1
				2	1	0	0	0
				2	1	0	2	1
				1	0	0	1	0
	031	51	8	2	0	0	0	1
				3	2	0	0	0
				3	0	0	0	0
				0	1	0	0	0
				2	1	0	1	0
				2	0	1	1	1
				4	1	0	1	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	034	34	9	SCREENING	23		29		5	4
				V1 (WEEK 0)	21		27		3	2
				V3 (WEEK 12)	15	-6	24	-3	6	
				V4 (WEEK 24)	21	0	27	0	6	
				V5 (WEEK 36)	27	6	35	8	5	1
				V6 (WEEK 52)	35	14	42	15	6	2
				V7 (WEEK 56)	39	18	48	21	5	2
	041	41	12	SCREENING	18		27		6	
				V1 (WEEK 0)	16		24		7	
				V3 (WEEK 12)	18	2	28	4	7	
				V4 (WEEK 24)	16	0	25	1	6	
				V5 (WEEK 36)	16	0	25	1	7	
				V6 (WEEK 52)	18	2	28	4	7	1
				V7 (WEEK 56)	14	-2	23	-1	6	
	044	44	12	SCREENING	23		33		7	
				V1 (WEEK 0)	24		34		8	1
				V3 (WEEK 12)	25	1	34	0	7	
				V4 (WEEK 24)	28	4	38	4	7	1
				V5 (WEEK 36)	34	10	44	10	7	2

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	034	34	9	2	6	0	2		
				2	6	0	1	3	
				2	9	0	3	1	
				2	6	0	3	2	
				3	8	1	5	4	
				3	7	2	4	4	
				3	9	2	4	6	
	041	41	12	0	9	0		3	
				0	8	0		3	
				0	10	0		2	
				0	9	0		2	
				0	9	0			
				0	10	0		2	
				0	9	0		1	
	044	44	12	1	10	2	1	4	
				1	10	1	1	3	
				1	9	1	1	2	
				0	10	2	1	4	
				1	10	3	1	3	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	034	34	9	3	3	1	1	2
				4	3	0	0	3
				3	0	0	0	0
				2	2	1	2	1
				4	3	0	0	1
				6	2	1	2	3
				5	4	2	3	3
	041	41	12	8	1	0	0	0
				4	1	0	0	1
				6	1	1	0	1
				6	1	0	0	1
				7	2	0	0	0
				6	1	0	0	1
				4	2	0	0	1
	044	44	12	7	0	1	0	0
				6	1	0	1	1
				9	2	0	1	1
				7	2	1	2	1
				8	3	1	2	3

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	044	44	12	V6 (WEEK 52)	38	14	48	14	8	2
				V7 (WEEK 56)	31	7	41	7	8	
	045	61	11	SCREENING	19		26		6	1
				V1 (WEEK 0)	13		18		5	
				V3 (WEEK 12)	14	1	19	1	5	
				V4 (WEEK 24)	12	-1	16	-2	5	
				V5 (WEEK 36)	20	7	26	8	6	
				V6 (WEEK 52)	35	22	43	25	8	
				V7 (WEEK 56)	34	21	42	24	7	
	047	64	11	SCREENING	15		25		8	
				V1 (WEEK 0)	9		19		6	
				V3 (WEEK 12)	13	4	23	4	6	
				V4 (WEEK 24)	15	6	25	6	7	
				V5 (WEEK 36)	13	4	23	4	6	
				V6 (WEEK 52)	16	7	26	7	7	
				V7 (WEEK 56)	13	4	22	3	7	
	049	90	21	SCREENING	18		28		7	1
				V1 (WEEK 0)	15		25		7	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	044	44	12	1	10	4	1	5	
				1	10	4	1	4	
	045	61	11	0	7	1		1	
				1	5	1		1	
				0	5	1		1	
				0	4	1			
				0	6	2			
				1	8	3		4	
				0	8	3		2	
	047	64	11	0	10	1		2	
				1	10	0			
				1	10	1		2	
1				10	0				
1				10	0		1		
1				10	0	1	3		
1				9	0		4		
049	90	21	1	10	0		5		
			1	10	0		4		

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	044	44	12	10	2	2	2	1
				8	1	1	2	1
	045	61	11	2	3	2	2	1
				1	1	1	1	1
				1	1	2	2	1
				2	1	1	2	0
				2	3	2	3	1
				6	5	1	2	3
				7	5	3	2	3
	047	64	11	3	0	0	1	0
				2	0	0	0	0
				3	0	0	0	0
				3	2	1	0	1
				4	1	0	0	0
				3	0	0	1	0
				1	0	0	0	0
	049	90	21	4	0	0	1	0
				2	0	0	0	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	049	90	21	V3 (WEEK 12)	13	-2	22	-3	5	
				V4 (WEEK 24)	18	3	27	2	6	
				V5 (WEEK 36)	19	4	29	4	6	
				V6 (WEEK 52)						
				V7 (WEEK 56)						
	051	92	21	SCREENING	17		27		8	1
				V1 (WEEK 0)	15		25		7	1
				V3 (WEEK 12)	17	2	27	2	7	1
				V4 (WEEK 24)	13	-2	23	-2	8	
				V5 (WEEK 36)	14	-1	24	-1	7	
				V6 (WEEK 52)	18	3	28	3	8	
				V7 (WEEK 56)	17	2	27	2	7	
	056	75	5	SCREENING	11		15		5	1
				V1 (WEEK 0)	14		21		5	1
				V3 (WEEK 12)	7	-7	16	-5	4	
				V4 (WEEK 24)	11	-3	18	-3	5	2
				V5 (WEEK 36)	9	-5	15	-6	4	1
				V6 (WEEK 52)	7	-7	15	-6	4	
				V7 (WEEK 56)	10	-4	17	-4	5	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	049	90	21	1	9	0		6	
				1	9	0		6	
				1	10	0		5	
	051	92	21	0	10	0		3	
				1	10	0		3	
				0	10	0		6	
				0	10	0		3	
				0	10	0		5	
				0	10	0		5	
				1	10	1		5	
	056	75	5	1	4	0			
				1	7	0			
				0	9	0			
				1	7	0			
				0	6	0			
				0	8	0			
				0	7	0		1	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	049	90	21	1	0	0	0	0
				5	0	0	0	0
				7	0	0	0	0
	051	92	21	5	0	0	0	0
				2	0	0	1	0
				2	0	0	1	0
				2	0	0	0	0
				2	0	0	0	0
				4	0	0	1	0
				2	0	0	1	0
	056	75	5	3	0	0	1	0
				5	0	0	1	1
				2	0	0	0	1
				2	0	0	1	0
				3	0	0	1	0
				2	0	0	1	0
				4	0	0	0	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	058	110	1	SCREENING	31		41		8	3
				V1 (WEEK 0)	32		42		9	2
				V3 (WEEK 12)	33	1	43	1	8	2
				V4 (WEEK 24)	29	-3	39	-3	8	1
				V5 (WEEK 36)	35	3	45	3	9	
				V6 (WEEK 52)	42	10	52	10	9	3
				V7 (WEEK 56)	41	9	51	9	8	
	059	116	1	SCREENING	9		13		6	
				V1 (WEEK 0)	9		16		6	
				V3 (WEEK 12)	9	0	17	1	6	
				V4 (WEEK 24)	14	5	19	3	7	
				V5 (WEEK 36)	11	2	17	1	6	1
				V6 (WEEK 52)	21	12	30	14	7	
				V7 (WEEK 56)	20	11	24	8	6	1
	065	84	16	SCREENING	31		40		9	3
				V1 (WEEK 0)	43		53		9	4
				V3 (WEEK 12)	28	-15	37	-16	8	3
				V4 (WEEK 24)	37	-6	47	-6	9	2
				V5 (WEEK 36)						

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	058	110	1	0	10	1	1	3	
				0	10	1	1	5	
				1	10	2		2	
				0	10	2		2	
				0	10	3		4	
				0	10	3	1	4	
				0	10	3	2	3	
	059	116	1	0	4	0			
				0	7	0			
				0	8	0			
				0	5	0		1	
				0	6	1			
				0	9	2	1	2	
				0	4	1			
	065	84	16	0	9	3		2	
				0	10	2	2	4	
				0	9	2			
				0	10	4		2	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	058	110	1	9	0	2	2	2
				8	2	0	2	2
				9	5	1	2	1
				7	5	1	2	1
				8	3	3	3	2
				11	3	2	3	3
				12	5	2	3	3
	059	116	1		0	1	2	0
				0	0	1	1	1
				2	0	0	1	0
				4	0	1	1	0
				2	0	0	1	0
				5	0	1	2	1
				7	3	1	1	0
	065	84	16	4	3	0	4	3
				7	4	4	4	3
				3	3	3	3	3
				5	4	4	4	3

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	065	84	16	V6 (WEEK 52) V7 (WEEK 56)						
	068	85	16	SCREENING V1 (WEEK 0) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52) V7 (WEEK 56)	11 13 13 14 15 23 19	 0 1 2 10 6	18 19 19 21 22 31 27	 0 2 3 12 8	5 5 6 6 6 6 6	1 1 1 1 1
	069	100	23	SCREENING V1 (WEEK 0) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52) V7 (WEEK 56)	13 17 14 7 10 8 12	 -3 -10 -7 -9 -5	19 26 20 12 17 15 18	 -6 -14 -9 -11 -8	5 5 7 3 4 4 4	
	072	106	18	SCREENING V1 (WEEK 0)	18 26		27 36		7 8	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	065	84	16						
	068	85	16	0	7	0		2	
				0	6	0		2	
				0	6	0		1	
				0	7	0			
				0	7	0		2	
				0	8	1		4	
				0	8	0		3	
	069	100	23	1	6	0		1	
				1	9	0	1	3	
				1	6	0			
				1	5	0			
				1	7	0			
				1	7	0			
				1	6	0			
	072	106	18	1	9	0		3	
				2	10	1		3	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	065	84	16					
	068	85	16	1	2	0	0	0
				3	2	0	0	0
				2	2	0	0	1
				3	2	1	1	1
				4	1	0	1	0
				5	0	2	2	2
				3	0	2	2	2
	069	100	23	5	0	0	1	0
				6	1	0	0	0
				5	1	0	0	0
				3	0	0	0	0
				5	0	0	0	0
				3	0	0	0	0
				7	0	0	0	0
	072	106	18	6	0	0	0	1
				7	2	1	1	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	072	106	18	V3 (WEEK 12)	29	3	39	3	8	1
				V4 (WEEK 24)	32	6	42	6	9	2
				V5 (WEEK 36)	28	2	38	2	8	
				V6 (WEEK 52)	32	6	42	6	9	
				V7 (WEEK 56)	26	0	36	0	8	1
	079	57	13	SCREENING	22		31		7	1
				V1 (WEEK 0)	26		34		8	2
				V3 (WEEK 12)	16	-10	24	-10	6	1
				V4 (WEEK 24)	35	9	45	11	10	2
				V5 (WEEK 36)	28	2	38	4	8	
				V6 (WEEK 52)	33	7	43	9	8	1
				V7 (WEEK 56)	27	1	37	3	7	1
	082	26	17	SCREENING	19		27		6	1
				V1 (WEEK 0)	15		24		6	
				V3 (WEEK 12)	19	4	27	3	5	
				V4 (WEEK 24)	18	3	25	1	4	
				V5 (WEEK 36)	16	1	25	1	6	
				V6 (WEEK 52)	21	6	31	7	7	1
				V7 (WEEK 56)	16	1	23	-1	3	1

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores					
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	072	106	18	1	10	2	2	5	
				1	10	1		5	
				1	10	1		2	
				1	10	1	1	3	
				1	10	2	1	4	
	079	57	13	1	9	2	2	3	
				1	8	1	1	3	
				1	8	1	1	1	
				1	10	1	1	4	
				3	10	1	2	4	
				1	10	0	2	5	
				2	10	1	2	4	
	082	26	17	1	8	0		2	
				1	9	0	1	2	
				1	8	0	1	2	
				1	7	1	1	2	
				1	9	0	1	2	
				1	10	0	1	2	
				1	7	1	1	2	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	072	106	18	9	1	0	0	0
				9	4	0	0	1
				10	3	1	1	1
				11	3	1	1	1
				7	1	0	1	0
	079	57	13	6	0	0	0	0
				8	1	0	1	0
				5	0	0	0	0
				12	2	0	1	1
				7	0	0	1	2
				12	1	0	2	1
				6	1	0	2	1
	082	26	17	8	1	0	0	0
				5	0	0	0	0
				9	1	0	0	0
				9	0	0	0	0
				6	0	0	0	0
				9	0	0	0	0
				7	0	0	0	0

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference From Baseline	Total	Difference From Baseline	Derived Word Recall Score	Derived Commands Score
Placebo	084	28	17	SCREENING	27		37		6	2
				V1 (WEEK 0)	29		39		7	2
				V3 (WEEK 12)	25	-4	35	-4	7	1
				V4 (WEEK 24)	24	-5	34	-5	7	1
				V5 (WEEK 36)	28	-1	36	-3	7	1
				V6 (WEEK 52)	22	-7	31	-8	7	2
				V7 (WEEK 56)	27	-2	37	-2	7	2
	086	112	21	SCREENING	19		28		7	
				V1 (WEEK 0)	21		31		6	
				V3 (WEEK 12)	17	-4	27	-4	5	
				V4 (WEEK 24)	19	-2	29	-2	6	
				V5 (WEEK 36)	17	-4	27	-4	5	1
				V6 (WEEK 52)	19	-2	29	-2	5	
				V7 (WEEK 56)	17	-4	26	-5	5	1
	088	40	16	SCREENING	20		25		6	1
				V1 (WEEK 0)	20		30		6	1
				V3 (WEEK 12)	33	13	43	13	6	2
				V4 (WEEK 24)	38	18	48	18	7	2
				V5 (WEEK 36)	41	21	51	21	7	3

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Derived Scores									
Treat- ment	Random No.	CRF Book No.	Site ID	Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score	
Placebo	084	28	17	2	10	1	1	3	
				2	10	1	1	2	
				2	10	1	2	3	
				1	10	1	2	2	
				2	8	1	2	4	
				2	9	0	1	2	
				2	10	1	2	2	
	086	112	21	0	9	0		2	
				1	10	0		3	
				0	10	0		4	
				0	10	0		4	
				0	10	0		4	
				0	10	0		4	
				0	9	0		4	
	088	40	16	1	5	1		3	
				0	10	1		2	
				0	10	3	1	5	
				1	10	3	2	5	
				1	10	4	2	4	

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	084	28	17	10	1	0	1	0
				11	1	1	1	0
				7	1	0	1	0
				9	1	0	0	0
				11	0	0	0	0
				6	2	0	0	0
				8	3	0	0	0
	086	112	21	9	0	0	1	0
				10	1	0	0	0
				8	0	0	0	0
				8	1	0	0	0
				7	0	0	0	0
				9	0	0	1	0
				7	0	0	0	0
	088	40	16	2	1	2	2	1
				2	2	2	2	2
				5	3	3	3	2
				12	2	2	1	1
				8	4	3	3	2

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Unmodified ADAS-cog		Modified ADAS-cog		Derived Scores	
					Total	Difference	Total	Difference	Derived Word Recall Score	Derived Commands Score
						From Baseline		From Baseline		
Placebo	088	40	16	V6 (WEEK 52) V7 (WEEK 56)						

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Constructional Praxis Score	Derived Delayed Word Recall Score	Derived Naming Objects Score	Derived Ideational Praxis Score	Derived Orientation Score
Placebo	088	40	16					

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Listing 16.2.6.10: Alzheimers Disease Assessment Scale (ADAS-cog)

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Treat- ment	Random No.	CRF Book No.	Site ID	Derived Scores				
				Derived Word Recognition Task Score	Derived Remembering Score	Derived Language Score	Derived Word Finding Score	Derived Comprehension Score
Placebo	088	40	16					

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
ACI-91	002	1	SCREENING	24	
			V1 (WEEK 0)	25	
			V4 (WEEK 24)	25	0
			V6 (WEEK 52)	19	-6
	004	1	SCREENING	24	
			V1 (WEEK 0)	20	
			V4 (WEEK 24)		
			V6 (WEEK 52)		
	006	2	SCREENING	26	
			V1 (WEEK 0)	28	
			V4 (WEEK 24)	24	-4
			V6 (WEEK 52)	22	-6
	010	1	SCREENING	24	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)		
			V6 (WEEK 52)		
	012	1	SCREENING	24	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	26	2
			V6 (WEEK 52)	24	0

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
ACI-91	014	4	SCREENING	22	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	22	-2
			V6 (WEEK 52)	22	-2
	015	4	SCREENING	20	
			V1 (WEEK 0)	21	
			V4 (WEEK 24)	23	2
			V6 (WEEK 52)	21	0
	017	5	SCREENING	24	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	21	-3
			V6 (WEEK 52)	20	-4
	019	5	SCREENING	22	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	24	0
			V6 (WEEK 52)	23	-1
	023	4	SCREENING	21	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	11	-11
			V6 (WEEK 52)	10	-12

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
ACI-91	027	20	SCREENING	26	
			V1 (WEEK 0)	25	
			V4 (WEEK 24)	26	1
			V6 (WEEK 52)	26	1
	030	8	SCREENING	18	
			V1 (WEEK 0)	20	
			V4 (WEEK 24)	13	-7
			V6 (WEEK 52)	7	-13
	032	8	SCREENING	26	
			V1 (WEEK 0)	28	
			V4 (WEEK 24)		
			V6 (WEEK 52)		
	033	9	SCREENING	23	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	23	-1
			V6 (WEEK 52)	22	-2
	042	12	SCREENING	18	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	13	-6
			V6 (WEEK 52)	12	-7

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
ACI-91	043	12	SCREENING	22	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)	20	-3
			V6 (WEEK 52)		
	046	11	SCREENING	18	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	17	-2
			V6 (WEEK 52)	17	-2
	048	11	SCREENING	24	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)	24	1
			V6 (WEEK 52)	22	-1
	050	21	SCREENING	21	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)	22	-1
			V6 (WEEK 52)	20	-3
	052	21	SCREENING	21	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)	16	-7
			V6 (WEEK 52)	19	-4

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
ACI-91	055	5	SCREENING	20	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)		
			V6 (WEEK 52)	24	2
	057	1	SCREENING	18	
			V1 (WEEK 0)	21	
			V4 (WEEK 24)	11	-10
			V6 (WEEK 52)		
	066	16	SCREENING	21	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)		
			V6 (WEEK 52)		
	067	16	SCREENING	26	
			V1 (WEEK 0)	27	
			V4 (WEEK 24)		
			V6 (WEEK 52)		
	071	18	SCREENING	21	
			V1 (WEEK 0)	21	
			V4 (WEEK 24)	19	-2
			V6 (WEEK 52)	16	-5

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
ACI-91	080	13	SCREENING	25	
			V1 (WEEK 0)	28	
			V4 (WEEK 24)		
			V6 (WEEK 52)	23	-5
	081	17	SCREENING	19	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	16	-3
			V6 (WEEK 52)	14	-5
	083	17	SCREENING	18	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	19	0
			V6 (WEEK 52)	19	0
	087	16	SCREENING	25	
			V1 (WEEK 0)	26	
			V4 (WEEK 24)	15	-11
			V6 (WEEK 52)	22	-4
	089	5	SCREENING	19	
			V1 (WEEK 0)	21	
			V4 (WEEK 24)	17	-4
			V6 (WEEK 52)	5	-16

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
ACI-91	093	17	SCREENING	17	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	20	1
			V6 (WEEK 52)	11	-8
	097	12	SCREENING	19	
			V1 (WEEK 0)	18	
			V4 (WEEK 24)		
			V6 (WEEK 52)		
Placebo	001	1	SCREENING	21	
			V1 (WEEK 0)	18	
			V4 (WEEK 24)	16	-2
			V6 (WEEK 52)	12	-6
	003	1	SCREENING	19	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	14	-8
			V6 (WEEK 52)		
	005	2	SCREENING	24	
			V1 (WEEK 0)	25	
			V4 (WEEK 24)	26	1
			V6 (WEEK 52)	24	-1

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
Placebo	009	1	SCREENING	18	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	22	0
			V6 (WEEK 52)	17	-5
	011	1	SCREENING	23	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	17	-5
			V6 (WEEK 52)	16	-6
	013	4	SCREENING	21	
			V1 (WEEK 0)	21	
			V4 (WEEK 24)	21	0
			V6 (WEEK 52)	23	2
	016	4	SCREENING	25	
			V1 (WEEK 0)	26	
			V4 (WEEK 24)	26	0
			V6 (WEEK 52)	25	-1
	018	5	SCREENING	19	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	7	-12
			V6 (WEEK 52)	8	-11

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
Placebo	020	5	SCREENING	18	
			V1 (WEEK 0)	9	
			V4 (WEEK 24)		
			V6 (WEEK 52)		
	024	4	SCREENING	20	
			V1 (WEEK 0)	18	
			V4 (WEEK 24)	21	3
			V6 (WEEK 52)	14	-4
	028	20	SCREENING	19	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	20	-2
			V6 (WEEK 52)	13	-9
	029	8	SCREENING	25	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	26	2
			V6 (WEEK 52)	22	-2
	031	8	SCREENING	23	
			V1 (WEEK 0)	27	
			V4 (WEEK 24)	25	-2
			V6 (WEEK 52)	25	-2

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
Placebo	034	9	SCREENING	19	
			V1 (WEEK 0)	18	
			V4 (WEEK 24)	21	3
			V6 (WEEK 52)	17	-1
	041	12	SCREENING	22	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)	25	2
			V6 (WEEK 52)	24	1
	044	12	SCREENING	21	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	22	0
			V6 (WEEK 52)	15	-7
	045	11	SCREENING	24	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	27	3
			V6 (WEEK 52)	18	-6
	047	11	SCREENING	22	
			V1 (WEEK 0)	26	
			V4 (WEEK 24)	27	1
			V6 (WEEK 52)	23	-3

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
Placebo	049	21	SCREENING	19	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	21	-1
			V6 (WEEK 52)		
	051	21	SCREENING	23	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	23	-1
			V6 (WEEK 52)	20	-4
	056	5	SCREENING	25	
			V1 (WEEK 0)	26	
			V4 (WEEK 24)	25	-1
			V6 (WEEK 52)	28	2
	058	1	SCREENING	20	
			V1 (WEEK 0)	18	
			V4 (WEEK 24)	19	1
			V6 (WEEK 52)	16	-2
	059	1	SCREENING	26	
			V1 (WEEK 0)	26	
			V4 (WEEK 24)	26	0
			V6 (WEEK 52)	24	-2

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
Placebo	065	16	SCREENING	18	
			V1 (WEEK 0)	18	
			V4 (WEEK 24)	16	-2
			V6 (WEEK 52)		
	068	16	SCREENING	24	
			V1 (WEEK 0)	26	
			V4 (WEEK 24)	26	0
			V6 (WEEK 52)	26	0
	069	23	SCREENING	24	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	23	-1
			V6 (WEEK 52)	28	4
	072	18	SCREENING	20	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	17	-2
			V6 (WEEK 52)	19	0
	079	13	SCREENING	21	
			V1 (WEEK 0)	19	
			V4 (WEEK 24)	15	-4
			V6 (WEEK 52)	15	-4

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Listing 16.2.6.11: Mini-Mental State Examination (MMSE)

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Treat- ment	Random No.	Site ID	Visit	MMSE Score (Derived)	MMSE Difference to baseline
Placebo	082	17	SCREENING	20	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)	20	-3
			V6 (WEEK 52)	22	-1
	084	17	SCREENING	20	
			V1 (WEEK 0)	22	
			V4 (WEEK 24)	20	-2
			V6 (WEEK 52)	18	-4
	086	21	SCREENING	23	
			V1 (WEEK 0)	23	
			V4 (WEEK 24)	26	3
			V6 (WEEK 52)	25	2
	088	16	SCREENING	23	
			V1 (WEEK 0)	24	
			V4 (WEEK 24)	19	-5
			V6 (WEEK 52)		

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	002	46	1	SCREENING	10	37.76
				V1 (WEEK 0)	10	36.48
				V3 (WEEK 12)	10	42.37
				V4 (WEEK 24)	10	36.85
				V5 (WEEK 36)	10	29.96
				V6 (WEEK 52)	10	29.91
				V7 (WEEK 56)	10	29.10
	004	47	1	SCREENING	10	25.78
				V1 (WEEK 0)	10	28.32
				V3 (WEEK 12)	0	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	006	8	2	SCREENING	10	35.30
				V1 (WEEK 0)	7	
				V3 (WEEK 12)	10	28.16
				V4 (WEEK 24)	10	26.07
				V5 (WEEK 36)	10	27.92
				V6 (WEEK 52)	10	28.50
				V7 (WEEK 56)	10	23.40

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	010	10	1	SCREENING	10	25.63
				V1 (WEEK 0)	10	25.67
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	012	67	1	SCREENING	9	
				V1 (WEEK 0)	10	22.09
				V3 (WEEK 12)	7	
				V4 (WEEK 24)	7	
				V5 (WEEK 36)	4	
				V6 (WEEK 52)	7	
				V7 (WEEK 56)	5	
	014	22	4	SCREENING	10	33.22
				V1 (WEEK 0)	10	32.31
				V3 (WEEK 12)	10	34.97
				V4 (WEEK 24)	10	34.28
				V5 (WEEK 36)	10	34.78
				V6 (WEEK 52)	10	35.10
				V7 (WEEK 56)	10	37.23

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	015	23	4	SCREENING	9	
				V1 (WEEK 0)	10	28.78
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	10	30.76
				V6 (WEEK 52)	9	
				V7 (WEEK 56)	10	32.43
	017	17	5	SCREENING	10	33.70
				V1 (WEEK 0)	10	32.87
				V3 (WEEK 12)	10	30.40
				V4 (WEEK 24)	10	29.73
				V5 (WEEK 36)	10	32.11
				V6 (WEEK 52)	10	29.54
				V7 (WEEK 56)	10	33.12
	019	19	5	SCREENING	10	36.59
				V1 (WEEK 0)	10	30.92
				V3 (WEEK 12)	10	31.58
				V4 (WEEK 24)	10	32.63
				V5 (WEEK 36)	10	33.85
				V6 (WEEK 52)	10	30.86
				V7 (WEEK 56)	10	37.58

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	023	71	4	SCREENING	10	22.38
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	10	18.93
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	9	
				V7 (WEEK 56)	9	
	027	87	20	SCREENING	9	
				V1 (WEEK 0)	10	35.72
				V3 (WEEK 12)	10	28.87
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	9	
				V7 (WEEK 56)	10	40.78
	030	50	8	SCREENING	9	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	7	
				V6 (WEEK 52)	6	
				V7 (WEEK 56)	9	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	032	52	8	SCREENING	10	24.42
				V1 (WEEK 0)	10	27.00
				V3 (WEEK 12)	0	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	033	33	9	SCREENING	9	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	9	
				V7 (WEEK 56)	9	
	042	70	12	SCREENING	8	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	10	17.19
				V5 (WEEK 36)	10	16.05
				V6 (WEEK 52)	8	
				V7 (WEEK 56)	7	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	043	43	12	SCREENING	10	22.04
				V1 (WEEK 0)	10	20.78
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	8	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	046	62	11	SCREENING	10	17.71
				V1 (WEEK 0)	3	
				V3 (WEEK 12)	10	19.25
				V4 (WEEK 24)	10	20.11
				V5 (WEEK 36)	10	21.63
				V6 (WEEK 52)	10	22.70
				V7 (WEEK 56)	10	20.11
	048	104	11	SCREENING	10	26.51
				V1 (WEEK 0)	10	32.05
				V3 (WEEK 12)	10	30.60
				V4 (WEEK 24)	8	
				V5 (WEEK 36)	10	35.33
				V6 (WEEK 52)	10	29.90
				V7 (WEEK 56)	10	28.86

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	050	93	21	SCREENING	10	21.69
				V1 (WEEK 0)	10	23.18
				V3 (WEEK 12)	10	23.08
				V4 (WEEK 24)	10	22.78
				V5 (WEEK 36)	10	24.64
				V6 (WEEK 52)	10	23.29
				V7 (WEEK 56)	10	26.40
	052	91	21	SCREENING	10	18.03
				V1 (WEEK 0)	10	19.70
				V3 (WEEK 12)	10	18.73
				V4 (WEEK 24)	10	19.27
				V5 (WEEK 36)	10	19.22
				V6 (WEEK 52)	10	20.52
				V7 (WEEK 56)	10	20.30
	055	76	5	SCREENING	9	
				V1 (WEEK 0)	8	
				V3 (WEEK 12)	0	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	5	
				V7 (WEEK 56)	0	

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	057	68	1	SCREENING	5	
				V1 (WEEK 0)	5	
				V3 (WEEK 12)	3	
				V4 (WEEK 24)	3	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	066	83	16	SCREENING	10	21.67
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	3	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	067	38	16	SCREENING	10	42.18
				V1 (WEEK 0)	10	43.32
				V3 (WEEK 12)	0	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	071	105	18	SCREENING	10	15.62
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	10	20.08
				V6 (WEEK 52)	4	
				V7 (WEEK 56)	10	18.92
	080	59	13	SCREENING	10	29.01
				V1 (WEEK 0)	10	27.15
				V3 (WEEK 12)	10	24.21
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	081	25	17	SCREENING	10	29.60
				V1 (WEEK 0)	10	27.85
				V3 (WEEK 12)	10	30.62
				V4 (WEEK 24)	10	25.01
				V5 (WEEK 36)	10	25.92
				V6 (WEEK 52)	10	19.09
				V7 (WEEK 56)	10	20.85

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	083	27	17	SCREENING	10	22.99
				V1 (WEEK 0)	10	24.30
				V3 (WEEK 12)	10	27.13
				V4 (WEEK 24)	10	23.74
				V5 (WEEK 36)	10	20.36
				V6 (WEEK 52)	10	25.46
				V7 (WEEK 56)	10	23.02
	087	39	16	SCREENING	10	25.86
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	10	20.37
				V4 (WEEK 24)	10	20.30
				V5 (WEEK 36)	10	21.86
				V6 (WEEK 52)	9	
				V7 (WEEK 56)	9	
	089	74	5	SCREENING	7	
				V1 (WEEK 0)	8	
				V3 (WEEK 12)	7	
				V4 (WEEK 24)	1	
				V5 (WEEK 36)	6	
				V6 (WEEK 52)	5	
				V7 (WEEK 56)	4	
		54	16	V3 (WEEK 12)	10	21.18

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
ACI-91	093	29	17	SCREENING	10	23.52
				V1 (WEEK 0)	10	23.52
				V3 (WEEK 12)	10	26.74
				V4 (WEEK 24)	10	25.88
				V5 (WEEK 36)	10	21.85
				V6 (WEEK 52)	10	19.87
				V7 (WEEK 56)	10	19.22
	097	69	12	SCREENING	10	14.36
				V1 (WEEK 0)	8	
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
Placebo	001	48	1	SCREENING	7	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	8	
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	3	
				V7 (WEEK 56)	5	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	003	45	1	SCREENING	6	
				V1 (WEEK 0)	7	
				V3 (WEEK 12)	4	
				V4 (WEEK 24)	1	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	005	5	2	SCREENING	10	30.91
				V1 (WEEK 0)	10	31.04
				V3 (WEEK 12)	10	33.16
				V4 (WEEK 24)	10	30.73
				V5 (WEEK 36)	10	32.23
				V6 (WEEK 52)	10	32.22
				V7 (WEEK 56)	10	34.88
	009	11	1	SCREENING	9	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	10	22.55
				V4 (WEEK 24)	10	25.90
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	9	
				V7 (WEEK 56)	6	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	011	65	1	SCREENING	10	22.77
				V1 (WEEK 0)	10	23.45
				V3 (WEEK 12)	10	24.40
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	6	
				V7 (WEEK 56)	6	
	013	21	4	SCREENING	10	28.81
				V1 (WEEK 0)	10	29.15
				V3 (WEEK 12)	10	30.41
				V4 (WEEK 24)	10	32.94
				V5 (WEEK 36)	10	34.06
				V6 (WEEK 52)	10	29.17
				V7 (WEEK 56)	10	33.47
	016	24	4	SCREENING	10	44.18
				V1 (WEEK 0)	10	43.36
				V3 (WEEK 12)	10	46.15
				V4 (WEEK 24)	10	44.88
				V5 (WEEK 36)	10	42.71
				V6 (WEEK 52)	10	36.69
				V7 (WEEK 56)	10	33.56

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	018	18	5	SCREENING	8	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	7	
				V5 (WEEK 36)	8	
				V6 (WEEK 52)	8	
				V7 (WEEK 56)	7	
	020	20	5	SCREENING	8	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	0	
				V4 (WEEK 24)	0	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	024	72	4	SCREENING	10	21.60
				V1 (WEEK 0)	10	24.27
				V3 (WEEK 12)	10	21.75
				V4 (WEEK 24)	10	26.75
				V5 (WEEK 36)	10	26.60
				V6 (WEEK 52)	10	27.05
				V7 (WEEK 56)	7	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	028	88	20	SCREENING	10	18.65
				V1 (WEEK 0)	10	25.92
				V3 (WEEK 12)	10	24.18
				V4 (WEEK 24)	10	23.33
				V5 (WEEK 36)	10	28.00
				V6 (WEEK 52)	10	21.23
				V7 (WEEK 56)	10	21.91
	029	49	8	SCREENING	10	27.18
				V1 (WEEK 0)	10	27.42
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	10	31.66
				V5 (WEEK 36)	10	32.04
				V6 (WEEK 52)	10	30.54
				V7 (WEEK 56)	10	32.20
	031	51	8	SCREENING	10	28.39
				V1 (WEEK 0)	10	33.20
				V3 (WEEK 12)	10	37.11
				V4 (WEEK 24)	10	33.22
				V5 (WEEK 36)	10	36.19
				V6 (WEEK 52)	10	38.02
				V7 (WEEK 56)	10	37.46

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	034	34	9	SCREENING	5	
				V1 (WEEK 0)	5	
				V3 (WEEK 12)	6	
				V4 (WEEK 24)	6	
				V5 (WEEK 36)	6	
				V6 (WEEK 52)	5	
				V7 (WEEK 56)	6	
	041	41	12	SCREENING	10	28.51
				V1 (WEEK 0)	10	26.50
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	8	
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	9	
				V7 (WEEK 56)	10	35.28
	044	44	12	SCREENING	9	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	10	20.16
				V6 (WEEK 52)	10	20.03
				V7 (WEEK 56)	9	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	045	61	11	SCREENING	10	31.09
				V1 (WEEK 0)	10	31.51
				V3 (WEEK 12)	10	34.56
				V4 (WEEK 24)	10	32.40
				V5 (WEEK 36)	10	34.81
				V6 (WEEK 52)	10	21.00
				V7 (WEEK 56)	10	25.31
	047	64	11	SCREENING	8	
				V1 (WEEK 0)	8	
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	8	
				V5 (WEEK 36)	8	
				V6 (WEEK 52)	8	
				V7 (WEEK 56)	8	
	049	90	21	SCREENING	10	24.46
				V1 (WEEK 0)	10	20.49
				V3 (WEEK 12)	10	24.25
				V4 (WEEK 24)	10	23.96
				V5 (WEEK 36)	10	24.38
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	051	92	21	SCREENING	10	27.29
				V1 (WEEK 0)	10	28.34
				V3 (WEEK 12)	10	32.12
				V4 (WEEK 24)	10	28.80
				V5 (WEEK 36)	10	29.66
				V6 (WEEK 52)	10	30.79
				V7 (WEEK 56)	10	30.04
	056	75	5	SCREENING	10	27.98
				V1 (WEEK 0)	10	30.42
				V3 (WEEK 12)	1	
				V4 (WEEK 24)	9	
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	10	36.84
				V7 (WEEK 56)	9	
	058	110	1	SCREENING	5	
				V1 (WEEK 0)	5	
				V3 (WEEK 12)	5	
				V4 (WEEK 24)	4	
				V5 (WEEK 36)	5	
				V6 (WEEK 52)	4	
				V7 (WEEK 56)	4	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	059	116	1	SCREENING	6	
				V1 (WEEK 0)	7	
				V3 (WEEK 12)	5	
				V4 (WEEK 24)	5	
				V5 (WEEK 36)	5	
				V6 (WEEK 52)	5	
				V7 (WEEK 56)	4	
	065	84	16	SCREENING	9	
				V1 (WEEK 0)	6	
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	8	
				V5 (WEEK 36)	0	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	
	068	85	16	SCREENING	10	29.73
				V1 (WEEK 0)	10	30.17
				V3 (WEEK 12)	10	29.47
				V4 (WEEK 24)	10	29.17
				V5 (WEEK 36)	10	29.06
				V6 (WEEK 52)	10	26.78
				V7 (WEEK 56)	7	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	069	100	23	SCREENING	9	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	10	31.98
				V4 (WEEK 24)	10	31.11
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	10	30.67
				V7 (WEEK 56)	10	35.38
	072	106	18	SCREENING	10	21.57
				V1 (WEEK 0)	10	17.36
				V3 (WEEK 12)	10	19.35
				V4 (WEEK 24)	10	15.88
				V5 (WEEK 36)	10	17.02
				V6 (WEEK 52)	10	17.64
				V7 (WEEK 56)	10	17.99
	079	57	13	SCREENING	8	
				V1 (WEEK 0)	8	
				V3 (WEEK 12)	8	
				V4 (WEEK 24)	8	
				V5 (WEEK 36)	8	
				V6 (WEEK 52)	8	
				V7 (WEEK 56)	8	

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	082	26	17	SCREENING	8	
				V1 (WEEK 0)	10	33.06
				V3 (WEEK 12)	10	32.73
				V4 (WEEK 24)	10	32.57
				V5 (WEEK 36)	10	30.82
				V6 (WEEK 52)	10	27.51
				V7 (WEEK 56)	10	28.00
	084	28	17	SCREENING	10	20.78
				V1 (WEEK 0)	10	23.07
				V3 (WEEK 12)	10	26.35
				V4 (WEEK 24)	10	24.50
				V5 (WEEK 36)	9	
				V6 (WEEK 52)	10	24.26
				V7 (WEEK 56)	10	21.94
	086	112	21	SCREENING	10	20.23
				V1 (WEEK 0)	10	21.64
				V3 (WEEK 12)	10	26.83
				V4 (WEEK 24)	10	23.22
				V5 (WEEK 36)	10	28.41
				V6 (WEEK 52)	10	25.91
				V7 (WEEK 56)	10	32.78

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Listing 16.2.6.12: Composite NTB z-score

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Treat- ment	Random No.	CRF Book No.	Site ID	Visit	Number of non-missing sub-test scores	NTB composite z-score
Placebo	088	40	16	SCREENING	8	
				V1 (WEEK 0)	9	
				V3 (WEEK 12)	9	
				V4 (WEEK 24)	5	
				V5 (WEEK 36)	3	
				V6 (WEEK 52)	0	
				V7 (WEEK 56)	0	

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	002	1	V1 (WEEK 0)	2	
			V3 (WEEK 12)	2.5	0.5
			V4 (WEEK 24)	4.5	2.5
			V5 (WEEK 36)	5	3
			V6 (WEEK 52)	5	3
	004	1	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	006	2	V1 (WEEK 0)	6	
			V3 (WEEK 12)		
			V4 (WEEK 24)	10	4
			V5 (WEEK 36)	9	3
			V6 (WEEK 52)	13	7
	010	1	V1 (WEEK 0)	6	
			V3 (WEEK 12)	6	0
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	012	1	V1 (WEEK 0)	3	

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	012	1	V3 (WEEK 12)	3	0
			V4 (WEEK 24)	5	2
			V5 (WEEK 36)	5	2
			V6 (WEEK 52)	6	3
	014	4	V1 (WEEK 0)	5	
			V3 (WEEK 12)	4.5	-0.5
			V4 (WEEK 24)	4.5	-0.5
			V5 (WEEK 36)	6	1
			V6 (WEEK 52)	6	1
	015	4	V1 (WEEK 0)	7	
			V3 (WEEK 12)	7	0
			V4 (WEEK 24)	7	0
			V5 (WEEK 36)	8	1
			V6 (WEEK 52)	9	2
	017	5	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	4.5	1
			V4 (WEEK 24)	4	0.5
			V5 (WEEK 36)	5	1.5
			V6 (WEEK 52)	6	2.5
	019	5	V1 (WEEK 0)	4	
			V3 (WEEK 12)	7	3

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	019	5	V4 (WEEK 24)	7	3
			V5 (WEEK 36)	9	5
			V6 (WEEK 52)	6.5	2.5
	023	4	V1 (WEEK 0)	4	
			V3 (WEEK 12)	4	0
			V4 (WEEK 24)	5.5	1.5
			V5 (WEEK 36)	7	3
			V6 (WEEK 52)	8	4
	027	20	V1 (WEEK 0)	5.5	
			V3 (WEEK 12)	6	0.5
			V4 (WEEK 24)	6	0.5
			V5 (WEEK 36)	4.5	-1
			V6 (WEEK 52)	5	-0.5
	030	8	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	5	1.5
			V4 (WEEK 24)	5	1.5
			V5 (WEEK 36)	14	10.5
			V6 (WEEK 52)	14	10.5
	032	8	V1 (WEEK 0)	3	
			V3 (WEEK 12)	4.5	1.5
			V4 (WEEK 24)		

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	032	8	V5 (WEEK 36)		
			V6 (WEEK 52)		
	033	9	V1 (WEEK 0)	6	
			V3 (WEEK 12)	6	0
			V4 (WEEK 24)	6.5	0.5
			V5 (WEEK 36)	8	2
			V6 (WEEK 52)	7	1
	042	12	V1 (WEEK 0)	7	
			V3 (WEEK 12)	10	3
			V4 (WEEK 24)	12	5
			V5 (WEEK 36)	12	5
			V6 (WEEK 52)	12	5
	043	12	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	8	4.5
			V4 (WEEK 24)	16	12.5
			V5 (WEEK 36)		
			V6 (WEEK 52)	18	14.5
	046	11	V1 (WEEK 0)	8	
			V3 (WEEK 12)	9	1
			V4 (WEEK 24)	8	0
			V5 (WEEK 36)	6	-2

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	046	11	V6 (WEEK 52)	10	2
	048	11	V1 (WEEK 0)	6.5	
			V3 (WEEK 12)	6.5	0
			V4 (WEEK 24)	8	1.5
			V5 (WEEK 36)	6	-0.5
			V6 (WEEK 52)	9	2.5
	050	21	V1 (WEEK 0)	2.5	
			V3 (WEEK 12)	2.5	0
			V4 (WEEK 24)	2.5	0
			V5 (WEEK 36)	2	-0.5
			V6 (WEEK 52)	2	-0.5
	052	21	V1 (WEEK 0)	1	
			V3 (WEEK 12)	1.5	0.5
			V4 (WEEK 24)	2	1
			V5 (WEEK 36)	2.5	1.5
			V6 (WEEK 52)	3.5	2.5
	055	5	V1 (WEEK 0)	4	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)	2.5	-1.5

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	057	1	V1 (WEEK 0)	4	
			V3 (WEEK 12)	5	1
			V4 (WEEK 24)	9	5
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	066	16	V1 (WEEK 0)	7	
			V3 (WEEK 12)	11	4
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	067	16	V1 (WEEK 0)	4.5	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	071	18	V1 (WEEK 0)	5.5	
			V3 (WEEK 12)	5.5	0
			V4 (WEEK 24)	5.5	0
			V5 (WEEK 36)	5.5	0
			V6 (WEEK 52)	8	2.5
	080	13	V1 (WEEK 0)	3	

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	080	13	V3 (WEEK 12)	7	4
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	081	17	V1 (WEEK 0)	7	
			V3 (WEEK 12)	6	-1
			V4 (WEEK 24)	7	0
			V5 (WEEK 36)	7	0
			V6 (WEEK 52)	11	4
	083	17	V1 (WEEK 0)	7	
			V3 (WEEK 12)	7	0
			V4 (WEEK 24)	7	0
			V5 (WEEK 36)	11	4
			V6 (WEEK 52)	11	4
	087	16	V1 (WEEK 0)	5	
			V3 (WEEK 12)	9	4
			V4 (WEEK 24)	9	4
			V5 (WEEK 36)	12	7
			V6 (WEEK 52)	12	7
	089	5	V1 (WEEK 0)	10	
			V3 (WEEK 12)	12	2

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
ACI-91	089	5	V4 (WEEK 24)	9	-1
			V5 (WEEK 36)	15	5
			V6 (WEEK 52)	14	4
	093	17	V1 (WEEK 0)	8	
			V3 (WEEK 12)	8	0
			V4 (WEEK 24)	8	0
			V5 (WEEK 36)	11	3
			V6 (WEEK 52)	11	3
	097	12	V1 (WEEK 0)	11	
			V3 (WEEK 12)	12	1
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
Placebo	001	1	V1 (WEEK 0)	11	
			V3 (WEEK 12)	11	0
			V4 (WEEK 24)	11	0
			V5 (WEEK 36)	11	0
			V6 (WEEK 52)	11	0
	003	1	V1 (WEEK 0)	4	
			V3 (WEEK 12)	5	1
			V4 (WEEK 24)	8	4

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	003	1	V5 (WEEK 36)		
			V6 (WEEK 52)		
	005	2	V1 (WEEK 0)	7	
			V3 (WEEK 12)	9	2
			V4 (WEEK 24)	9	2
			V5 (WEEK 36)		
			V6 (WEEK 52)	10	3
	009	1	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	3.5	0
			V4 (WEEK 24)	3.5	0
			V5 (WEEK 36)	4	0.5
			V6 (WEEK 52)	4	0.5
	011	1	V1 (WEEK 0)	5	
			V3 (WEEK 12)	5	0
			V4 (WEEK 24)	5	0
			V5 (WEEK 36)	5	0
			V6 (WEEK 52)	6	1
	013	4	V1 (WEEK 0)	6.5	
			V3 (WEEK 12)	6.5	0
			V4 (WEEK 24)	6.5	0
			V5 (WEEK 36)	6.5	0

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	013	4	V6 (WEEK 52)	8.5	2
	016	4	V1 (WEEK 0)	4	
			V3 (WEEK 12)	4	0
			V4 (WEEK 24)	4	0
			V5 (WEEK 36)	4.5	0.5
			V6 (WEEK 52)	5.5	1.5
	018	5	V1 (WEEK 0)	6.5	
			V3 (WEEK 12)	8	1.5
			V4 (WEEK 24)	10	3.5
			V5 (WEEK 36)	10	3.5
			V6 (WEEK 52)	10	3.5
	020	5	V1 (WEEK 0)	9	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	024	4	V1 (WEEK 0)	6	
			V3 (WEEK 12)	7	1
			V4 (WEEK 24)	8	2
			V5 (WEEK 36)	8	2
			V6 (WEEK 52)	8	2

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	028	20	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	4.5	1
			V4 (WEEK 24)	5	1.5
			V5 (WEEK 36)	5.5	2
			V6 (WEEK 52)	6.5	3
	029	8	V1 (WEEK 0)	4	
			V3 (WEEK 12)	4	0
			V4 (WEEK 24)	5.5	1.5
			V5 (WEEK 36)	6	2
			V6 (WEEK 52)	6	2
	031	8	V1 (WEEK 0)	4	
			V3 (WEEK 12)	5	1
			V4 (WEEK 24)	4	0
			V5 (WEEK 36)	6	2
			V6 (WEEK 52)	5	1
	034	9	V1 (WEEK 0)	10	
			V3 (WEEK 12)	8.5	-1.5
			V4 (WEEK 24)	9	-1
			V5 (WEEK 36)	8	-2
			V6 (WEEK 52)	9	-1
	041	12	V1 (WEEK 0)	5	

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	041	12	V3 (WEEK 12)	4	-1
			V4 (WEEK 24)	4.5	-0.5
			V5 (WEEK 36)	4.5	-0.5
			V6 (WEEK 52)	5.5	0.5
	044	12	V1 (WEEK 0)	4	
			V3 (WEEK 12)	4.5	0.5
			V4 (WEEK 24)	5	1
			V5 (WEEK 36)	6	2
			V6 (WEEK 52)	8	4
	045	11	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	5	1.5
			V4 (WEEK 24)	3	-0.5
			V5 (WEEK 36)	6	2.5
			V6 (WEEK 52)	8	4.5
	047	11	V1 (WEEK 0)	5.5	
			V3 (WEEK 12)	5	-0.5
			V4 (WEEK 24)	5	-0.5
			V5 (WEEK 36)	6	0.5
			V6 (WEEK 52)	5	-0.5
	049	21	V1 (WEEK 0)	10	
			V3 (WEEK 12)	10	0

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	049	21	V4 (WEEK 24)	10	0
			V5 (WEEK 36)	10	0
			V6 (WEEK 52)		
	051	21	V1 (WEEK 0)	1	
			V3 (WEEK 12)	1	0
			V4 (WEEK 24)	1	0
			V5 (WEEK 36)	1	0
			V6 (WEEK 52)	1	0
	056	5	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	3.5	0
			V4 (WEEK 24)	3.5	0
			V5 (WEEK 36)	3	-0.5
			V6 (WEEK 52)	1	-2.5
	058	1	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	4	0.5
			V4 (WEEK 24)	4	0.5
			V5 (WEEK 36)	4	0.5
			V6 (WEEK 52)	4	0.5
	059	1	V1 (WEEK 0)	3	
			V3 (WEEK 12)	3	0
			V4 (WEEK 24)	3	0

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	059	1	V5 (WEEK 36)	3	0
			V6 (WEEK 52)	3	0
	065	16	V1 (WEEK 0)	8	
			V3 (WEEK 12)	8	0
			V4 (WEEK 24)	8	0
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	068	16	V1 (WEEK 0)	4	
			V3 (WEEK 12)	4	0
			V4 (WEEK 24)	6.5	2.5
			V5 (WEEK 36)	9	5
			V6 (WEEK 52)	8	4
	069	23	V1 (WEEK 0)	1	
			V3 (WEEK 12)	0.5	-0.5
			V4 (WEEK 24)	0.5	-0.5
			V5 (WEEK 36)	1.5	0.5
			V6 (WEEK 52)	1	0
	072	18	V1 (WEEK 0)	3	
			V3 (WEEK 12)	3	0
			V4 (WEEK 24)	4.5	1.5
			V5 (WEEK 36)	5.5	2.5

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	072	18	V6 (WEEK 52)	5.5	2.5
	079	13	V1 (WEEK 0)	3.5	
			V3 (WEEK 12)	9	5.5
			V4 (WEEK 24)	6	2.5
			V5 (WEEK 36)	6	2.5
			V6 (WEEK 52)	7	3.5
	082	17	V1 (WEEK 0)	5	
			V3 (WEEK 12)	3.5	-1.5
			V4 (WEEK 24)	3.5	-1.5
			V5 (WEEK 36)	4.5	-0.5
			V6 (WEEK 52)	4.5	-0.5
	084	17	V1 (WEEK 0)	4.5	
			V3 (WEEK 12)	4.5	0
			V4 (WEEK 24)	4.5	0
			V5 (WEEK 36)	4.5	0
			V6 (WEEK 52)	8	3.5
	086	21	V1 (WEEK 0)	4.5	
			V3 (WEEK 12)	4.5	0
			V4 (WEEK 24)	4.5	0
			V5 (WEEK 36)	4	-0.5
			V6 (WEEK 52)	4	-0.5

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Listing 16.2.6.13: Clinical Dementia Rating (CDR) Scale sum of boxes

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Treat- ment	Random No.	Site ID	Visit	CDR Sum Of Boxes	Difference From Baseline CDR
Placebo	088	16	V1 (WEEK 0)	7	
			V3 (WEEK 12)	11	4
			V4 (WEEK 24)	13	6
			V5 (WEEK 36)	15	8
			V6 (WEEK 52)		

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	002	1	V1 (WEEK 0)	90	
			V3 (WEEK 12)	87.5	-2.5
			V4 (WEEK 24)	87.5	-2.5
			V5 (WEEK 36)	80	-10
			V6 (WEEK 52)	82.5	-7.5
	004	1	V1 (WEEK 0)	90	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	006	2	V1 (WEEK 0)	70.97	
			V3 (WEEK 12)		
			V4 (WEEK 24)	46.15	-24.82
			V5 (WEEK 36)	52.5	-18.47
			V6 (WEEK 52)	37.5	-33.47
	010	1	V1 (WEEK 0)	67.5	
			V3 (WEEK 12)	67.5	0
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	012	1	V1 (WEEK 0)	100	

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	012	1	V3 (WEEK 12)	100	0
			V4 (WEEK 24)	100	0
			V5 (WEEK 36)	77.5	-22.5
			V6 (WEEK 52)	80	-20
	014	4	V1 (WEEK 0)	77.5	
			V3 (WEEK 12)	78.38	0.88
			V4 (WEEK 24)	80	2.5
			V5 (WEEK 36)	82.05	4.55
			V6 (WEEK 52)	74.36	-3.14
	015	4	V1 (WEEK 0)	67.5	
			V3 (WEEK 12)	71.79	4.29
			V4 (WEEK 24)	72.5	5
			V5 (WEEK 36)	69.23	1.73
			V6 (WEEK 52)	75	7.5
	017	5	V1 (WEEK 0)	97.06	
			V3 (WEEK 12)	83.33	-13.73
			V4 (WEEK 24)	84.38	-12.68
			V5 (WEEK 36)	55.26	-41.8
			V6 (WEEK 52)	47.22	-49.84
	019	5	V1 (WEEK 0)	78.38	
			V3 (WEEK 12)	69.23	-9.15

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	019	5	V4 (WEEK 24)	72.97	-5.41
			V5 (WEEK 36)	60	-18.38
			V6 (WEEK 52)	72.97	-5.41
	023	4	V1 (WEEK 0)	93.94	
			V3 (WEEK 12)	88.89	-5.05
			V4 (WEEK 24)	89.19	-4.75
			V5 (WEEK 36)	86.11	-7.83
			V6 (WEEK 52)	77.14	-16.8
	027	20	V1 (WEEK 0)	82.5	
			V3 (WEEK 12)	80	-2.5
			V4 (WEEK 24)	94.87	12.37
			V5 (WEEK 36)	87.5	5
			V6 (WEEK 52)	77.5	-5
	030	8	V1 (WEEK 0)	75	
			V3 (WEEK 12)	75	0
			V4 (WEEK 24)	67.5	-7.5
			V5 (WEEK 36)	25	-50
			V6 (WEEK 52)	45	-30
	032	8	V1 (WEEK 0)	100	
			V3 (WEEK 12)	100	0
			V4 (WEEK 24)		

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	032	8	V5 (WEEK 36)		
			V6 (WEEK 52)		
	033	9	V1 (WEEK 0)	94.12	
			V3 (WEEK 12)	83.78	-10.34
			V4 (WEEK 24)	72.5	-21.62
			V5 (WEEK 36)	66.67	-27.45
			V6 (WEEK 52)	67.5	-26.62
	042	12	V1 (WEEK 0)	45	
			V3 (WEEK 12)	22.5	-22.5
			V4 (WEEK 24)	20	-25
			V5 (WEEK 36)	37.5	-7.5
			V6 (WEEK 52)	17.5	-27.5
	043	12	V1 (WEEK 0)	94.59	
			V3 (WEEK 12)	25	-69.59
			V4 (WEEK 24)	7.5	-87.09
			V5 (WEEK 36)		
			V6 (WEEK 52)	0	-94.59
	046	11	V1 (WEEK 0)	65	
			V3 (WEEK 12)	50	-15
			V4 (WEEK 24)	50	-15
			V5 (WEEK 36)	42.5	-22.5

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	046	11	V6 (WEEK 52)	47.5	-17.5
	048	11	V1 (WEEK 0)	67.5	
			V3 (WEEK 12)	55	-12.5
			V4 (WEEK 24)	60	-7.5
			V5 (WEEK 36)	57.5	-10
			V6 (WEEK 52)	52.5	-15
	050	21	V1 (WEEK 0)	100	
			V3 (WEEK 12)	91.43	-8.57
			V4 (WEEK 24)	72.5	-27.5
			V5 (WEEK 36)	97.22	-2.78
			V6 (WEEK 52)	94.29	-5.71
	052	21	V1 (WEEK 0)	100	
			V3 (WEEK 12)	100	0
			V4 (WEEK 24)	100	0
			V5 (WEEK 36)	100	0
			V6 (WEEK 52)	91.67	-8.33
	055	5	V1 (WEEK 0)	91.89	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)	100	8.11

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	057	1	V1 (WEEK 0)	80	
			V3 (WEEK 12)	72.5	-7.5
			V4 (WEEK 24)	42.5	-37.5
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	066	16	V1 (WEEK 0)	40	
			V3 (WEEK 12)	40	0
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	067	16	V1 (WEEK 0)	72.5	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)	97.5	25
	071	18	V1 (WEEK 0)	95	
			V3 (WEEK 12)	85	-10
			V4 (WEEK 24)	77.5	-17.5
			V5 (WEEK 36)	80	-15
			V6 (WEEK 52)	57.5	-37.5
	080	13	V1 (WEEK 0)	97.5	

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	080	13	V3 (WEEK 12)	65.79	-31.71
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	081	17	V1 (WEEK 0)	42.5	
			V3 (WEEK 12)	42.5	0
			V4 (WEEK 24)	42.5	0
			V5 (WEEK 36)	35	-7.5
			V6 (WEEK 52)	25	-17.5
	083	17	V1 (WEEK 0)	45	
			V3 (WEEK 12)	45	0
			V4 (WEEK 24)	20	-25
			V5 (WEEK 36)	35	-10
			V6 (WEEK 52)	45	0
	087	16	V1 (WEEK 0)	65	
			V3 (WEEK 12)	42.5	-22.5
			V4 (WEEK 24)	57.5	-7.5
			V5 (WEEK 36)	50	-15
			V6 (WEEK 52)	35	-30
	089	5	V1 (WEEK 0)	22.5	
			V3 (WEEK 12)	22.5	0

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
ACI-91	089	5	V4 (WEEK 24)	12.5	-10
			V5 (WEEK 36)	10	-12.5
			V6 (WEEK 52)	5	-17.5
	093	17	V1 (WEEK 0)	35	
			V3 (WEEK 12)	55	20
			V4 (WEEK 24)	50	15
			V5 (WEEK 36)	37.5	2.5
			V6 (WEEK 52)	37.5	2.5
	097	12	V1 (WEEK 0)	40	
			V3 (WEEK 12)	22.5	-17.5
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
Placebo	001	1	V1 (WEEK 0)	67.5	
			V3 (WEEK 12)	67.5	0
			V4 (WEEK 24)	70	2.5
			V5 (WEEK 36)	35	-32.5
			V6 (WEEK 52)	40	-27.5
	003	1	V1 (WEEK 0)	70	
			V3 (WEEK 12)	57.5	-12.5
			V4 (WEEK 24)	65	-5

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	003	1	V5 (WEEK 36)		
			V6 (WEEK 52)		
	005	2	V1 (WEEK 0)	50	
			V3 (WEEK 12)	73.33	23.33
			V4 (WEEK 24)	78.38	28.38
			V5 (WEEK 36)	74.36	24.36
			V6 (WEEK 52)	74.36	24.36
	009	1	V1 (WEEK 0)	82.5	
			V3 (WEEK 12)	87.5	5
			V4 (WEEK 24)	82.5	0
			V5 (WEEK 36)	95	12.5
			V6 (WEEK 52)	77.5	-5
	011	1	V1 (WEEK 0)	65.79	
			V3 (WEEK 12)	65	-0.79
			V4 (WEEK 24)	62.5	-3.29
			V5 (WEEK 36)	57.5	-8.29
			V6 (WEEK 52)		
	013	4	V1 (WEEK 0)	58.33	
			V3 (WEEK 12)	65	6.67
			V4 (WEEK 24)	65	6.67
			V5 (WEEK 36)	67.5	9.17

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	013	4	V6 (WEEK 52)	56.41	-1.92
	016	4	V1 (WEEK 0)	100	
			V3 (WEEK 12)	100	0
			V4 (WEEK 24)	100	0
			V5 (WEEK 36)	94.59	-5.41
			V6 (WEEK 52)	100	0
	018	5	V1 (WEEK 0)	57.5	
			V3 (WEEK 12)	45	-12.5
			V4 (WEEK 24)	50	-7.5
			V5 (WEEK 36)	56.41	-1.09
			V6 (WEEK 52)	52.5	-5
	020	5	V1 (WEEK 0)	62.5	
			V3 (WEEK 12)		
			V4 (WEEK 24)		
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	024	4	V1 (WEEK 0)	81.08	
			V3 (WEEK 12)	78.38	-2.7
			V4 (WEEK 24)	80.56	-0.52
			V5 (WEEK 36)	73.68	-7.4
			V6 (WEEK 52)	87.88	6.8

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	028	20	V1 (WEEK 0)	100	
			V3 (WEEK 12)	100	0
			V4 (WEEK 24)	100	0
			V5 (WEEK 36)	82.5	-17.5
			V6 (WEEK 52)	85	-15
	029	8	V1 (WEEK 0)	100	
			V3 (WEEK 12)	100	0
			V4 (WEEK 24)	90	-10
			V5 (WEEK 36)	85	-15
			V6 (WEEK 52)	82.5	-17.5
	031	8	V1 (WEEK 0)	90	
			V3 (WEEK 12)	72.5	-17.5
			V4 (WEEK 24)	67.5	-22.5
			V5 (WEEK 36)	82.5	-7.5
			V6 (WEEK 52)	80	-10
	034	9	V1 (WEEK 0)	55.56	
			V3 (WEEK 12)	37.5	-18.06
			V4 (WEEK 24)	35	-20.56
			V5 (WEEK 36)	45	-10.56
			V6 (WEEK 52)	55	-0.56
	041	12	V1 (WEEK 0)	88.89	

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	041	12	V3 (WEEK 12)	57.5	-31.39
			V4 (WEEK 24)	62.5	-26.39
			V5 (WEEK 36)	65	-23.89
			V6 (WEEK 52)	70	-18.89
	044	12	V1 (WEEK 0)	97.5	
			V3 (WEEK 12)	97.5	0
			V4 (WEEK 24)	97.5	0
			V5 (WEEK 36)	92.5	-5
			V6 (WEEK 52)	77.5	-20
	045	11	V1 (WEEK 0)	87.5	
			V3 (WEEK 12)	82.5	-5
			V4 (WEEK 24)	77.5	-10
			V5 (WEEK 36)	55	-32.5
			V6 (WEEK 52)	50	-37.5
	047	11	V1 (WEEK 0)	70	
			V3 (WEEK 12)	72.5	2.5
			V4 (WEEK 24)	75	5
			V5 (WEEK 36)	80	10
			V6 (WEEK 52)	80	10
	049	21	V1 (WEEK 0)	42.5	
			V3 (WEEK 12)	56.25	13.75

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	049	21	V4 (WEEK 24)	45	2.5
			V5 (WEEK 36)	41.67	-0.83
			V6 (WEEK 52)		
	051	21	V1 (WEEK 0)	100	
			V3 (WEEK 12)	97.22	-2.78
			V4 (WEEK 24)	92.11	-7.89
			V5 (WEEK 36)	88.57	-11.43
			V6 (WEEK 52)	100	0
	056	5	V1 (WEEK 0)	97.5	
			V3 (WEEK 12)	100	2.5
			V4 (WEEK 24)	95	-2.5
			V5 (WEEK 36)	100	2.5
			V6 (WEEK 52)	100	2.5
	058	1	V1 (WEEK 0)	80	
			V3 (WEEK 12)	90	10
			V4 (WEEK 24)	65	-15
			V5 (WEEK 36)	87.5	7.5
			V6 (WEEK 52)	67.5	-12.5
	059	1	V1 (WEEK 0)	92.5	
			V3 (WEEK 12)	90	-2.5
			V4 (WEEK 24)	90	-2.5

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	059	1	V5 (WEEK 36)	90	-2.5
			V6 (WEEK 52)	90	-2.5
	065	16	V1 (WEEK 0)	95	
			V3 (WEEK 12)	77.5	-17.5
			V4 (WEEK 24)	82.5	-12.5
			V5 (WEEK 36)		
			V6 (WEEK 52)		
	068	16	V1 (WEEK 0)	70	
			V3 (WEEK 12)	65	-5
			V4 (WEEK 24)	55	-15
			V5 (WEEK 36)	32.5	-37.5
			V6 (WEEK 52)	55	-15
	069	23	V1 (WEEK 0)	100	
			V3 (WEEK 12)	100	0
			V4 (WEEK 24)	95	-5
			V5 (WEEK 36)	97.5	-2.5
			V6 (WEEK 52)	91.89	-8.11
	072	18	V1 (WEEK 0)	80	
			V3 (WEEK 12)	82.5	2.5
			V4 (WEEK 24)	80	0
			V5 (WEEK 36)	85	5

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	072	18	V6 (WEEK 52)	90	10
	079	13	V1 (WEEK 0)	94.59	
			V3 (WEEK 12)	77.5	-17.09
			V4 (WEEK 24)	62.5	-32.09
			V5 (WEEK 36)	84.21	-10.38
			V6 (WEEK 52)	71.79	-22.8
	082	17	V1 (WEEK 0)	62.5	
			V3 (WEEK 12)	60	-2.5
			V4 (WEEK 24)	60	-2.5
			V5 (WEEK 36)	55	-7.5
			V6 (WEEK 52)	65	2.5
	084	17	V1 (WEEK 0)	50	
			V3 (WEEK 12)	47.5	-2.5
			V4 (WEEK 24)	40	-10
			V5 (WEEK 36)	40	-10
			V6 (WEEK 52)	45	-5
	086	21	V1 (WEEK 0)	62.86	
			V3 (WEEK 12)	58.33	-4.53
			V4 (WEEK 24)	62.5	-0.36
			V5 (WEEK 36)	58.33	-4.53
			V6 (WEEK 52)	72.97	10.11

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Listing 16.2.6.14: Disability Assessment in Dementia (DAD) Scale

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Treat- ment	Random No.	Site ID	Visit	DAD Percentage Total Score	Difference From Baseline DAD (%)
Placebo	088	16	V1 (WEEK 0)	45	
			V3 (WEEK 12)	32.5	-12.5
			V4 (WEEK 24)	15	-30
			V5 (WEEK 36)	12.5	-32.5
			V6 (WEEK 52)	2.5	-42.5

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	002	1	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	0	0	0	0
			V5 (WEEK 36)	2	2	2	2
			V6 (WEEK 52)	11	11	10	10
			V7 (WEEK 56)	6	6	5	5
	004	1	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)				
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				
	006	2	SCREENING				
			V1 (WEEK 0)	12		3	
			V2 (WEEK 4)	16	4	2	-1
			V3 (WEEK 12)	16	4	5	2
			V4 (WEEK 24)	18	6	4	1
			V5 (WEEK 36)	10	-2	3	0

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	006	2	V6 (WEEK 52)	46	34	15	12
			V7 (WEEK 56)	37	25	16	13
	010	1	SCREENING				
			V1 (WEEK 0)	9		8	
			V2 (WEEK 4)	7	-2	7	-1
			V3 (WEEK 12)	5	-4	5	-3
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				
	012	1	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	2	2	2	2
			V5 (WEEK 36)	2	2	3	3
			V6 (WEEK 52)	3	3	4	4
			V7 (WEEK 56)	0	0	0	0
	014	4	SCREENING				
			V1 (WEEK 0)	14		15	
			V2 (WEEK 4)	14	0	14	-1

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	014	4	V3 (WEEK 12)	12	-2	19	4
			V4 (WEEK 24)	8	-6	8	-7
			V5 (WEEK 36)	11	-3	11	-4
			V6 (WEEK 52)	24	10	19	4
			V7 (WEEK 56)	11	-3	12	-3
	015	4	SCREENING				
			V1 (WEEK 0)	5		4	
			V2 (WEEK 4)	5	0	2	-2
			V3 (WEEK 12)	5	0	3	-1
			V4 (WEEK 24)	5	0	3	-1
			V5 (WEEK 36)	5	0	4	0
			V6 (WEEK 52)	9	4	4	0
			V7 (WEEK 56)	13	8	5	1
	017	5	SCREENING				
			V1 (WEEK 0)	21		17	
			V2 (WEEK 4)	11	-10	7	-10
			V3 (WEEK 12)	7	-14	11	-6
			V4 (WEEK 24)	6	-15	9	-8
			V5 (WEEK 36)	24	3	22	5
			V6 (WEEK 52)	10	-11	12	-5
			V7 (WEEK 56)	11	-10	8	-9

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	019	5	SCREENING				
			V1 (WEEK 0)	5		4	
			V2 (WEEK 4)	21	16	13	9
			V3 (WEEK 12)	11	6	3	-1
			V4 (WEEK 24)	12	7	8	4
			V5 (WEEK 36)	18	13	8	4
			V6 (WEEK 52)	4	-1	5	1
			V7 (WEEK 56)	5	0	9	5
	023	4	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	1	1	2	2
			V3 (WEEK 12)	4	4	1	1
			V4 (WEEK 24)	9	9	1	1
			V5 (WEEK 36)	5	5	1	1
			V6 (WEEK 52)	3	3	1	1
			V7 (WEEK 56)	2	2	1	1
	027	20	SCREENING				
			V1 (WEEK 0)	42		13	
			V2 (WEEK 4)	44	2	9	-4
			V3 (WEEK 12)	32	-10	9	-4
			V4 (WEEK 24)	22	-20	0	-13
			V5 (WEEK 36)	25	-17	1	-12

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	027	20	V6 (WEEK 52)	18	-24	0	-13
			V7 (WEEK 56)	21	-21	0	-13
	030	8	SCREENING				
			V1 (WEEK 0)	2		1	
			V2 (WEEK 4)	0	-2	0	-1
			V3 (WEEK 12)	2	0	2	1
			V4 (WEEK 24)	1	-1	1	0
			V5 (WEEK 36)	1	-1	0	-1
			V6 (WEEK 52)	9	7	0	-1
			V7 (WEEK 56)	8	6	0	-1
	032	8	SCREENING				
			V1 (WEEK 0)	27		19	
			V2 (WEEK 4)	27	0	18	-1
			V3 (WEEK 12)	6	-21	11	-8
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)				
	033	9	SCREENING				
			V1 (WEEK 0)	7		3	
			V2 (WEEK 4)	8	1	2	-1

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	033	9	V3 (WEEK 12)	6	-1	3	0
			V4 (WEEK 24)	8	1	7	4
			V5 (WEEK 36)	7	0	2	-1
			V6 (WEEK 52)	9	2	5	2
			V7 (WEEK 56)	10	3	6	3
	042	12	SCREENING				
			V1 (WEEK 0)	54		32	
			V2 (WEEK 4)	38	-16	27	-5
			V3 (WEEK 12)	41	-13	44	12
			V4 (WEEK 24)	48	-6	44	12
			V5 (WEEK 36)	3	-51	0	-32
			V6 (WEEK 52)	14	-40	4	-28
			V7 (WEEK 56)	14	-40	4	-28
	043	12	SCREENING				
			V1 (WEEK 0)	12		6	
			V2 (WEEK 4)	8	-4	7	1
			V3 (WEEK 12)	36	24	17	11
			V4 (WEEK 24)	7	-5	10	4
			V5 (WEEK 36)				
			V6 (WEEK 52)	27	15	9	3
			V7 (WEEK 56)				

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	046	11	SCREENING				
			V1 (WEEK 0)	4		4	
			V2 (WEEK 4)	19	15	5	1
			V3 (WEEK 12)	16	12	7	3
			V4 (WEEK 24)	4	0	0	-4
			V5 (WEEK 36)	8	4	1	-3
			V6 (WEEK 52)	11	7	2	-2
			V7 (WEEK 56)	8	4	2	-2
	048	11	SCREENING				
			V1 (WEEK 0)	14		5	
			V2 (WEEK 4)	20	6	7	2
			V3 (WEEK 12)	11	-3	2	-3
			V4 (WEEK 24)	21	7	6	1
			V5 (WEEK 36)	8	-6	0	-5
			V6 (WEEK 52)	10	-4	8	3
			V7 (WEEK 56)	8	-6	4	-1
	050	21	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	23	23	21	21
			V3 (WEEK 12)	30	30	9	9
			V4 (WEEK 24)	0	0	0	0
			V5 (WEEK 36)	0	0	0	0

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	050	21	V6 (WEEK 52)	0	0	0	0
			V7 (WEEK 56)	0	0	0	0
	052	21	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	0	0	0	0
			V5 (WEEK 36)	0	0	0	0
			V6 (WEEK 52)	0	0	0	0
			V7 (WEEK 56)	0	0	0	0
	055	5	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)				
			V3 (WEEK 12)				
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)	0	0	0	0
			V7 (WEEK 56)				
	057	1	SCREENING				
			V1 (WEEK 0)	8		8	
			V2 (WEEK 4)	6	-2	6	-2

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	057	1	V3 (WEEK 12)	14	6	7	-1
			V4 (WEEK 24)	12	4	7	-1
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				
	066	16	SCREENING				
			V1 (WEEK 0)	35		29	
			V2 (WEEK 4)	47	12	23	-6
			V3 (WEEK 12)	44	9	21	-8
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				
	067	16	SCREENING				
			V1 (WEEK 0)	3		0	
			V2 (WEEK 4)	5	2	0	0
			V3 (WEEK 12)				
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)	6	3	5	5
			V7 (WEEK 56)				

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	071	18	SCREENING				
			V1 (WEEK 0)	7		3	
			V2 (WEEK 4)	8	1	4	1
			V3 (WEEK 12)	10	3	4	1
			V4 (WEEK 24)	6	-1	3	0
			V5 (WEEK 36)	10	3	4	1
			V6 (WEEK 52)	8	1	5	2
			V7 (WEEK 56)	10	3	4	1
	080	13	SCREENING				
			V1 (WEEK 0)	7		3	
			V2 (WEEK 4)	1	-6	0	-3
			V3 (WEEK 12)	28	21	21	18
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				
	081	17	SCREENING				
			V1 (WEEK 0)	3		3	
			V2 (WEEK 4)	0	-3	0	-3
			V3 (WEEK 12)	6	3	3	0
			V4 (WEEK 24)	6	3	3	0
			V5 (WEEK 36)	0	-3	0	-3

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	081	17	V6 (WEEK 52)	12	9	6	3
			V7 (WEEK 56)	10	7	6	3
	083	17	SCREENING				
			V1 (WEEK 0)	6		3	
			V2 (WEEK 4)	10	4	5	2
			V3 (WEEK 12)	10	4	6	3
			V4 (WEEK 24)	10	4	4	1
			V5 (WEEK 36)	8	2	5	2
			V6 (WEEK 52)	13	7	5	2
			V7 (WEEK 56)	9	3	3	0
	087	16	SCREENING				
			V1 (WEEK 0)	12		8	
			V2 (WEEK 4)	4	-8	2	-6
			V3 (WEEK 12)	20	8	0	-8
			V4 (WEEK 24)	15	3	8	0
			V5 (WEEK 36)	21	9	8	0
			V6 (WEEK 52)	18	6	12	4
			V7 (WEEK 56)	16	4	9	1
	089	5	SCREENING				
			V1 (WEEK 0)	15		3	
			V2 (WEEK 4)	15	0	3	0

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
ACI-91	089	5	V3 (WEEK 12)	12	-3	4	1
			V4 (WEEK 24)	16	1	5	2
			V5 (WEEK 36)	4	-11	0	-3
			V6 (WEEK 52)	28	13	7	4
			V7 (WEEK 56)	16	1	7	4
	093	17	SCREENING				
			V1 (WEEK 0)	6		3	
			V2 (WEEK 4)	8	2	4	1
			V3 (WEEK 12)	4	-2	2	-1
			V4 (WEEK 24)	8	2	5	2
			V5 (WEEK 36)	6	0	3	0
			V6 (WEEK 52)	6	0	3	0
			V7 (WEEK 56)	9	3	3	0
	097	12	SCREENING				
			V1 (WEEK 0)	2		7	
			V2 (WEEK 4)	1	-1	5	-2
			V3 (WEEK 12)	8	6	5	-2
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	001	1	SCREENING				
			V1 (WEEK 0)	3		3	
			V2 (WEEK 4)	4	1	3	0
			V3 (WEEK 12)	3	0	4	1
			V4 (WEEK 24)	2	-1	3	0
			V5 (WEEK 36)	14	11	10	7
			V6 (WEEK 52)	11	8	7	4
			V7 (WEEK 56)	11	8	8	5
	003	1	SCREENING				
			V1 (WEEK 0)	5		4	
			V2 (WEEK 4)	16	11	13	9
			V3 (WEEK 12)	8	3	9	5
			V4 (WEEK 24)	14	9	13	9
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				
	005	2	SCREENING				
			V1 (WEEK 0)	1		0	
			V2 (WEEK 4)	0	-1	0	0
			V3 (WEEK 12)	0	-1	0	0
			V4 (WEEK 24)	0	-1	0	0
			V5 (WEEK 36)	0	-1	0	0

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	005	2	V6 (WEEK 52)	8	7	1	1
			V7 (WEEK 56)	8	7	1	1
	009	1	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	0	0	0	0
			V5 (WEEK 36)	0	0	0	0
			V6 (WEEK 52)	3	3	3	3
			V7 (WEEK 56)	0	0	0	0
	011	1	SCREENING				
			V1 (WEEK 0)	15		12	
			V2 (WEEK 4)	2	-13	3	-9
			V3 (WEEK 12)	5	-10	4	-8
			V4 (WEEK 24)	14	-1	11	-1
			V5 (WEEK 36)	16	1	12	0
			V6 (WEEK 52)				
			V7 (WEEK 56)	9	-6	6	-6
	013	4	SCREENING				
			V1 (WEEK 0)	14		15	
			V2 (WEEK 4)	18	4	19	4

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	013	4	V3 (WEEK 12)	17	3	15	0
			V4 (WEEK 24)	24	10	18	3
			V5 (WEEK 36)	23	9	14	-1
			V6 (WEEK 52)	20	6	25	10
			V7 (WEEK 56)	34	20	27	12
	016	4	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	0	0	0	0
			V5 (WEEK 36)	3	3	3	3
			V6 (WEEK 52)	0	0	0	0
			V7 (WEEK 56)	0	0	0	0
	018	5	SCREENING				
			V1 (WEEK 0)	46		26	
			V2 (WEEK 4)	33	-13	18	-8
			V3 (WEEK 12)	40	-6	21	-5
			V4 (WEEK 24)	34	-12	22	-4
			V5 (WEEK 36)	27	-19	15	-11
			V6 (WEEK 52)	28	-18	16	-10
			V7 (WEEK 56)	40	-6	24	-2

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	020	5	SCREENING				
			V1 (WEEK 0)	48		33	
			V2 (WEEK 4)				
			V3 (WEEK 12)				
			V4 (WEEK 24)				
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				
	024	4	SCREENING				
			V1 (WEEK 0)	8		4	
			V2 (WEEK 4)	6	-2	2	-2
			V3 (WEEK 12)	6	-2	4	0
			V4 (WEEK 24)	4	-4	5	1
			V5 (WEEK 36)	5	-3	4	0
			V6 (WEEK 52)	11	3	4	0
			V7 (WEEK 56)	9	1	6	2
	028	20	SCREENING				
			V1 (WEEK 0)	5		5	
			V2 (WEEK 4)	12	7	0	-5
			V3 (WEEK 12)	7	2	0	-5
			V4 (WEEK 24)	3	-2	6	1
			V5 (WEEK 36)	4	-1	1	-4

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	028	20	V6 (WEEK 52)	10	5	5	0
			V7 (WEEK 56)	9	4	3	-2
	029	8	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	6	6	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	15	15	3	3
			V5 (WEEK 36)	14	14	0	0
			V6 (WEEK 52)	4	4	1	1
			V7 (WEEK 56)	12	12	0	0
	031	8	SCREENING				
			V1 (WEEK 0)	7		12	
			V2 (WEEK 4)	17	10	18	6
			V3 (WEEK 12)	11	4	11	-1
			V4 (WEEK 24)	14	7	20	8
			V5 (WEEK 36)	17	10	20	8
			V6 (WEEK 52)	12	5	16	4
			V7 (WEEK 56)	24	17	20	8
	034	9	SCREENING				
			V1 (WEEK 0)	1		2	
			V2 (WEEK 4)	0	-1	0	-2

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	034	9	V3 (WEEK 12)	2	1	3	1
			V4 (WEEK 24)	10	9	3	1
			V5 (WEEK 36)	12	11	5	3
			V6 (WEEK 52)	8	7	1	-1
			V7 (WEEK 56)	7	6	4	2
	041	12	SCREENING				
			V1 (WEEK 0)	1		4	
			V2 (WEEK 4)	7	6	8	4
			V3 (WEEK 12)	9	8	5	1
			V4 (WEEK 24)	6	5	9	5
			V5 (WEEK 36)	3	2	9	5
			V6 (WEEK 52)	0	-1	0	-4
			V7 (WEEK 56)	3	2	4	0
	044	12	SCREENING				
			V1 (WEEK 0)	6		2	
			V2 (WEEK 4)	2	-4	3	1
			V3 (WEEK 12)	3	-3	2	0
			V4 (WEEK 24)	2	-4	7	5
			V5 (WEEK 36)	3	-3	3	1
			V6 (WEEK 52)	3	-3	5	3
			V7 (WEEK 56)	0	-6	0	-2

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	045	11	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	2	2	0	0
			V5 (WEEK 36)	21	21	4	4
			V6 (WEEK 52)	20	20	5	5
			V7 (WEEK 56)	6	6	2	2
	047	11	SCREENING				
			V1 (WEEK 0)	17		7	
			V2 (WEEK 4)	19	2	5	-2
			V3 (WEEK 12)	7	-10	3	-4
			V4 (WEEK 24)	10	-7	3	-4
			V5 (WEEK 36)	14	-3	4	-3
			V6 (WEEK 52)	6	-11	2	-5
			V7 (WEEK 56)	11	-6	6	-1
	049	21	SCREENING				
			V1 (WEEK 0)	32		24	
			V2 (WEEK 4)	20	-12	6	-18
			V3 (WEEK 12)	32	0	4	-20
			V4 (WEEK 24)	25	-7	5	-19
			V5 (WEEK 36)	20	-12	8	-16

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	049	21	V6 (WEEK 52)				
			V7 (WEEK 56)				
	051	21	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	0	0	0	0
			V5 (WEEK 36)	0	0	0	0
			V6 (WEEK 52)	0	0	0	0
			V7 (WEEK 56)	0	0	0	0
	056	5	SCREENING				
			V1 (WEEK 0)	4		3	
			V2 (WEEK 4)	3	-1	1	-2
			V3 (WEEK 12)	0	-4	0	-3
			V4 (WEEK 24)	12	8	9	6
			V5 (WEEK 36)	0	-4	0	-3
			V6 (WEEK 52)	0	-4	0	-3
			V7 (WEEK 56)	0	-4	0	-3
	058	1	SCREENING				
			V1 (WEEK 0)	2		3	
			V2 (WEEK 4)	5	3	5	2

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	058	1	V3 (WEEK 12)	2	0	3	0
			V4 (WEEK 24)	2	0	4	1
			V5 (WEEK 36)	1	-1	3	0
			V6 (WEEK 52)	4	2	7	4
			V7 (WEEK 56)	10	8	9	6
	059	1	SCREENING				
			V1 (WEEK 0)	8		7	
			V2 (WEEK 4)	2	-6	3	-4
			V3 (WEEK 12)	5	-3	6	-1
			V4 (WEEK 24)	8	0	8	1
			V5 (WEEK 36)	6	-2	5	-2
			V6 (WEEK 52)	7	-1	3	-4
			V7 (WEEK 56)	0	-8	0	-7
	065	16	SCREENING				
			V1 (WEEK 0)	10		16	
			V2 (WEEK 4)	2	-8	7	-9
			V3 (WEEK 12)	7	-3	7	-9
			V4 (WEEK 24)	15	5	17	1
			V5 (WEEK 36)				
			V6 (WEEK 52)				
			V7 (WEEK 56)				

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	068	16	SCREENING				
			V1 (WEEK 0)	20		14	
			V2 (WEEK 4)	22	2	11	-3
			V3 (WEEK 12)	5	-15	3	-11
			V4 (WEEK 24)	34	14	19	5
			V5 (WEEK 36)	18	-2	8	-6
			V6 (WEEK 52)	20	0	10	-4
			V7 (WEEK 56)	27	7	14	0
	069	23	SCREENING				
			V1 (WEEK 0)	13		6	
			V2 (WEEK 4)	11	-2	4	-2
			V3 (WEEK 12)	0	-13	0	-6
			V4 (WEEK 24)	4	-9	6	0
			V5 (WEEK 36)	18	5	13	7
			V6 (WEEK 52)	10	-3	6	0
			V7 (WEEK 56)	4	-9	4	-2
	072	18	SCREENING				
			V1 (WEEK 0)	6		2	
			V2 (WEEK 4)	4	-2	2	0
			V3 (WEEK 12)	9	3	2	0
			V4 (WEEK 24)	6	0	3	1
			V5 (WEEK 36)	7	1	3	1

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	072	18	V6 (WEEK 52)	7	1	4	2
			V7 (WEEK 56)	6	0	3	1
	079	13	SCREENING				
			V1 (WEEK 0)	1		0	
			V2 (WEEK 4)	2	1	0	0
			V3 (WEEK 12)	0	-1	0	0
			V4 (WEEK 24)	6	5	1	1
			V5 (WEEK 36)	6	5	0	0
			V6 (WEEK 52)	1	0	0	0
			V7 (WEEK 56)	1	0	0	0
	082	17	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	4	4	2	2
			V4 (WEEK 24)	4	4	2	2
			V5 (WEEK 36)	4	4	3	3
			V6 (WEEK 52)	4	4	3	3
			V7 (WEEK 56)	0	0	0	0
	084	17	SCREENING				
			V1 (WEEK 0)	6		3	
			V2 (WEEK 4)	6	0	3	0

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Listing 16.2.6.15: Disability Assessment - Neuropsychiatric Inventory (NPI)

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Treat- ment	Random No.	Site ID	Visit	NPI Total score	Difference From Baseline NPI	NPI Total score (Distress)	Difference From Baseline NPI (Distress)
Placebo	084	17	V3 (WEEK 12)	4	-2	3	0
			V4 (WEEK 24)	6	0	3	0
			V5 (WEEK 36)	4	-2	3	0
			V6 (WEEK 52)	17	11	7	4
			V7 (WEEK 56)	17	11	8	5
	086	21	SCREENING				
			V1 (WEEK 0)	0		0	
			V2 (WEEK 4)	0	0	0	0
			V3 (WEEK 12)	0	0	0	0
			V4 (WEEK 24)	0	0	0	0
			V5 (WEEK 36)	0	0	0	0
			V6 (WEEK 52)	0	0	0	0
			V7 (WEEK 56)	0	0	0	0
	088	16	SCREENING				
			V1 (WEEK 0)	25		12	
			V2 (WEEK 4)	22	-3	15	3
			V3 (WEEK 12)	31	6	16	4
			V4 (WEEK 24)	39	14	15	3
			V5 (WEEK 36)	47	22	19	7
			V6 (WEEK 52)	44	19	14	2
			V7 (WEEK 56)	50	25	14	2

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	002	1	HEADACHE	2009-04-24	08:00	2009-04-28	12:00	MODERATE	NO	YES	RESOLVED
			DIARRHOEA	2009-05-05	22:30	2009-05-05	23:50	MILD	NO	YES	RESOLVED
			DIARRHOEA	2009-05-07	22:30	2009-05-07	23:59	MILD	NO	YES	RESOLVED
			DIARRHOEA	2009-05-08	22:00	2009-05-08	23:59	MILD	NO	YES	RESOLVED
			DIARRHOEA	2009-05-10	22:30	2009-05-10	23:59	MILD	NO	YES	RESOLVED
	004	1	BACK PAIN	2009-07-24	08:00	2009-07-31	22:00	MILD	NO	NO	RESOLVED
	006	2	HEADACHE	2010-11-10	09:00	2010-11-10	11:00	MILD	NO	NO	RESOLVED
	010	1	PAIN IN THE LEFT KNEE	2009-10-04	07:00	2009-11-20	07:00	MILD	NO	NO	RESOLVED WITH SEQUELAE
			INTERMITTENT DELUSIONAL SYMPTOMS	2009-10-16	10:00	2009-11-05	07:00	MILD	NO	NO	RESOLVED
			THROMBOSIS IN THE LEFT VENA FIBULARIS	2009-11-04	08:30			MODERATE	NO	NO	ONGOING
	012	1	RENEWED RIGHT LUMBOISCHIALGIA	2010-09-09	07:00			MODERATE	NO	NO	ONGOING
			INCREASE OF SGOT AND SGPT	2010-10-14	09:15	2010-11-29	08:45	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	002	1	HEADACHE	CONCOMITANT THERAPY	
			DIARRHOEA	NONE	
			DIARRHOEA	NONE	
			DIARRHOEA	NONE	
			DIARRHOEA	NONE	
	004	1	BACK PAIN	NONE	
	006	2	HEADACHE	CONCOMITANT THERAPY	
	010	1	PAIN IN THE LEFT KNEE	CONCOMITANT THERAPY, OTHER	ORTHOPADIC CHECK, DEGENERATIVE MENISCOPATHY
			INTERMITTENT DELUSIONAL SYMPTOMS	CONCOMITANT THERAPY	
			THROMBOSIS IN THE LEFT VENA FIBULARIS	CONCOMITANT THERAPY, OTHER	ANGIOLOGICAL CHECK
	012	1	RENEWED RIGHT LUMBOISCHIALGIA	CONCOMITANT THERAPY	
			INCREASE OF SGOT AND SGPT	OTHER	GP INFORMED,WHO CONTROLLED THE INCREASED SGPT AND SGOT WITH NORMALIZED VALUES AT 29.11.2010

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Listing 16.2.7.1: Adverse events

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				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	012	1	BRADYCARDIA	2010-10-14	09:30			MILD	NO	NO	ONGOING
	014	4	POSTPUNCTINAL HEADACHE	2009-11-02	13:00	2009-11-03	09:00	MILD	NO	NO	RESOLVED
			DISTAL RADIUS FRACTURE OF LEFT UPPER LIMB	2010-01-09	11:00	2010-02-09	11:00	MILD	NO	NO	RESOLVED
	015	4	DRY COUGH DUE TO RAMIPRIL	2010-04	00:00	2010-05-15	00:00	MILD	NO	NO	RESOLVED
	017	5	FASTER SATED	2009-08-06	00:00	2009-10-28	00:00	MODERATE	NO	YES	RESOLVED
			WEIGHT LOSS	2009-08-06	00:00	2009-10-14	00:00	MODERATE	NO	YES	RESOLVED
			XEROSTOMIA	2009-08-06	00:00	2009-10-28	00:00	MILD	NO	YES	RESOLVED
			COGNITIVE DECLINE	2009-08-09	00:00	2009-09-02	00:00	MODERATE	NO	YES	RESOLVED
			PAIN IN SHOULDER	2009-09-23	00:00	2009-09-26	00:00	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	012	1	BRADYCARDIA	OTHER	GP INFORMED, WHO DECIDED TO CONTROLL THE BRADYCARDIA BECAUSE OF NORMAL VALUES IN HER CONSULTING ROOM AND IN THE CASE OF ONGOING TO ARRANGE A CARDIOLOGICAL CHECK
	014	4	POSTPUNCTINAL HEADACHE DISTAL RADIUS FRACTURE OF LEFT UPPER LIMB	CONCOMITANT THERAPY OTHER	LIMB FIXATION
	015	4	DRY COUGH DUE TO RAMIPRIL	CONCOMITANT THERAPY, OTHER	RAMIPRIL WAS STOPPED AT 14/05/2010, CHANGE OF HYPERTENSION MEDICATION INTO CANDESARTAN
	017	5	FASTER SATED WEIGHT LOSS XEROSTOMIA COGNITIVE DECLINE PAIN IN SHOULDER	NONE NONE NONE NONE CONCOMITANT THERAPY	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	017	5	FUNGAL SKIN INFECTION	2009-10-28	00:00	2009-11-25	00:00	MILD	NO	NO	RESOLVED
			VOMITING	2009-12-20	00:00	2009-12-24	00:00	MILD	NO	NO	RESOLVED
			PAIN IN RIGHT SHOULDER	2010-07-26	08:00	2010-07-30	23:00	MILD	NO	NO	RESOLVED
	019	5	XEROSTOMIA	2010-05-11	08:00	2011-01-04	08:00	MILD	NO	YES	RESOLVED
	023	4	GENERAL DISCOMFORT OBSERVED BY SPOUSE	2010-07-20	08:00	2011-08-11	08:00	MILD	NO	NO	RESOLVED
			PAIN COCCYX	2010-07-20	08:00	2010-07-20	20:00	MILD	NO	NO	RESOLVED
			XEROSTOMIA	2010-07-21	08:00	2010-08-07	08:00	MILD	NO	NO	RESOLVED
			TINEA PEDIS	2010-08-17	09:00			MILD	NO	NO	ONGOING
			DIARRHEA	2010-08-24	17:00	2010-08-24	17:30	MILD	NO	NO	RESOLVED
			SINUSITIS	2010-12-09	08:30	2010-12-10	18:30	MILD	NO	NO	RESOLVED
			FREQUENT MICTURITION	2011-01-07	NK:NK			MILD	NO	NO	ONGOING
			BLADDER INFECTION	2011-01-26	08:00	2011-01-29	20:00	MILD	NO	NO	RESOLVED
			SLIGHT INCREASE OF QTC (445MS)	2011-03-21	12:22				NO		LOST TO FU
			SLIGHT INCREASE OF QTC (453MS)	2011-07-18	14:10				NO		LOST TO FU

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	017	5	FUNGAL SKIN INFECTION	CONCOMITANT THERAPY	
			VOMITING	NONE	
			PAIN IN RIGHT SHOULDER	CONCOMITANT THERAPY	
	019	5	XEROSTOMIA	NONE	
	023	4	GENERAL DISCOMFORT	NONE	
			OBSERVED BY SPOUSE		
			PAIN COCCYX	NONE	
			XEROSTOMIA	NONE	
			TINEA PEDIS	CONCOMITANT THERAPY	
			DIARRHEA	NONE	
			SINUSITIS	CONCOMITANT THERAPY	
			FREQUENT MICTURITION	CONCOMITANT THERAPY	
			BLADDER INFECTION	CONCOMITANT THERAPY	
			SLIGHT INCREASE OF QTC (445MS)	NONE	
			SLIGHT INCREASE OF QTC (453MS)	NONE	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	027	20	INTERMITTEND	2010-11-09	NK:NK	2011-06-01	NK:NK	MILD	NO	NO	RESOLVED
			TIREDDNESS								
			ADRENAL TUMOR	2011-02-11	00:00			MILD	NO	NO	ONGOING
			BENIGN								
			COIN SHAPED DENSITY	2011-02-11	00:00			MILD	NO	NO	ONGOING
			UNSPECIFIC IN THE								
			LUNG								
			PULMONARY EMPHYSEMA	2011-02-11	00:00			MILD	NO	NO	ONGOING
			URINARY TRACT	2011-04-12	00:00	2011-04-22	00:00	MILD	NO	NO	RESOLVED
			INFECTION								
			ATOPIC DERMATITIS	2011-07-22	00:00			MILD	NO	NO	ONGOING
			PNEUMONIA	2011-07-22	00:00	2011-08-01	00:00	MODERATE	YES	NO	RESOLVED
			URINARY TRACT	2011-10-25	00:00	2011-10-30	00:00	MILD	NO	NO	RESOLVED
			INFECTION								
	030	8	RECURRENT XEROSTOMIA	2010-04-01	NK:NK			MILD	NO	YES	ONGOING
			SLIGHT HEADACHE	2010-04-07	NK:NK	2010-04-07	NK:NK	MILD	NO	NO	RESOLVED
			URINARY TRACT	2010-06-17	NK:NK	2010-06-28	NK:NK	MILD	NO	NO	RESOLVED
			INFECTION								
			HEADACHE	2010-08-19	10:00	2010-08-22	10:00	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	027	20	INTERMITTEND	NONE	
			TIREDNESS		
			ADRENAL TUMOR	OTHER	EXAMINATION AT ENDOCRINOLOGY
			BENIGN		
			COIN SHAPED DENSITY	OTHER	SEND TO THE PULMONARY WARD
			UNSPECIFIC IN THE		
			LUNG		
			PULMONARY EMPHYSEMA	NONE	
			URINARY TRACT	CONCOMITANT THERAPY	
			INFECTION		
			ATOPIC DERMATITIS	CONCOMITANT THERAPY	
			PNEUMONIA	HOSPITALIZATION, CONCOMITANT THERAPY	
			URINARY TRACT	NONE	
			INFECTION		
	030	8	RECURRENT XEROSTOMIA	NONE	
			SLIGHT HEADACHE	NONE	
			URINARY TRACT	CONCOMITANT THERAPY	
			INFECTION		
			HEADACHE	NONE	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	030	8	HYPOSTHESIA RIGHT ARM	2010-09-03	NK:NK	2011-03-14	13:30	MILD	NO	NO	RESOLVED
			WORSENING OF ATAXIA RIGHT ARM	2010-09-03	NK:NK			MODERATE	NO	NO	ONGOING
			RECURRENT PAIN IN THE CHEST LEFT SIDE	2011-01-25	09:30	2011-02-01	15:00	MILD	NO	NO	RESOLVED
			STOMACHE PAIN	2011-02-11	10:00	2011-02-11	15:00	MILD	NO	NO	RESOLVED
			DYSPNEA	2011-02-28	11:00	2011-02-28	16:00	MILD	NO	NO	RESOLVED
			DYSPNEA	2011-03-05	09:00	2011-03-05	15:00	MILD	NO	NO	RESOLVED
			UPPER LIMB SHAKING	2011-03-14	12:30	2011-03-14	12:45	MILD	YES	YES	RESOLVED
			URINARY TRACT INFECTION	2011-03-14	14:00			MILD	NO	NO	ONGOING
	033	9	NAUSEA AND VOMITING	2011-03-28	NK:NK	2011-03-30	NK:NK	MODERATE	YES	NO	RESOLVED
			VERTIGO	2011-03-28	NK:NK	2011-03-30	NK:NK	MODERATE	YES	NO	RESOLVED
	042	12	FATIGUE	2010-05-29	00:00	2010-05-29	00:00	MILD	NO	YES	RESOLVED
			NOCTURNAL RESTLESSNESS AND EXCITATION	2010-08	00:00			MILD	NO	NO	ONGOING
			GASTRAL PAIN	2010-01-15	10:00	2010-01-17	10:00	MILD	NO	NO	RESOLVED
			DIARRHOE	2010-01-27	09:00	2010-01-27	12:00	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	030	8	HYPOSTHESIA RIGHT ARM	NONE	
			WORSENING OF ATAXIA RIGHT ARM	NONE	
			RECURRENT PAIN IN THE CHEST LEFT SIDE	NONE	
			STOMACHE PAIN	NONE	
			DYSPNEA	NONE	
			DYSPNEA	NONE	
			UPPER LIMB SHAKING	HOSPITALIZATION	
			URINARY TRACT INFECTION	NONE	
			NAUSEA AND VOMITING	HOSPITALIZATION	
			VERTIGO	HOSPITALIZATION	
	033	9	FATIGUE	NONE	
	042	12	NOCTURNAL RESTLESSNESS AND EXCITATION	CONCOMITANT THERAPY	
			GASTRAL PAIN	NONE	
			DIARRHOE	NONE	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	042	12	LOCAL DESORIENTATION	2009-12	17:00	2009-12	23:00	MILD	NO	NO	RESOLVED
	043	12	ANAEMIA OF UNKNOWN ORIGIN	2010-07	00:00			MILD	NO	NO	ONGOING
			OBSTIPATION	2010-05	00:00			MILD	NO	NO	ONGOING
			PARKINSON SYNDROME	2010-04	00:00			MILD	YES	NO	ONGOING
			VISIONS	2009-12-29	00:00			MILD	YES	YES	ONGOING
			RESTLESSNESS DURING NIGHT	2009-12-30	00:00			MILD	NO	NO	ONGOING
			INGUINAL INTERTRIGO BOTH SIDES	2010-01-27	00:00	2010-05	00:00	MILD	NO	NO	RESOLVED
			COLLAPSE AND DOWNFALL	2010-04-30	00:00	2010-04-30	00:00	MODERATE	YES	NO	RESOLVED
			HEAD LACERATION	2010-04-30	00:00	2010-05	00:00	MODERATE	YES	NO	RESOLVED WITH SEQUELAE
			HYPOTENSIVE EPISODE	2010-04-30	00:00	2010-04-30	17:00	MODERATE	YES	NO	RESOLVED
			PYREXIA OF UP TO 40 °C	2010-07-03	00:00	2010-07-04	00:00	MODERATE	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	042	12	LOCAL DESORIENTATION	NONE	
	043	12	ANAEMIA OF UNKNOWN ORIGIN	NONE	
			OBSTIPATION	CONCOMITANT THERAPY	
			PARKINSON SYNDROME	HOSPITALIZATION	
			VISIONS	HOSPITALIZATION, CONCOMITANT THERAPY	
			RESTLESSNESS DURING NIGHT	CONCOMITANT THERAPY	
			INGUINAL INTERTRIGO BOTH SIDES	CONCOMITANT THERAPY	
			COLLAPSE AND DOWNFALL	HOSPITALIZATION	
			HEAD LACERATION	HOSPITALIZATION	
			HYPOTENSIVE EPISODE PYREXIA OF UP TO 40 °C	HOSPITALIZATION CONCOMITANT THERAPY	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	043	12	DOWNFALL WITH CONTUSION AND RESULTING HAEMATOMA OF RIGHT THIGH	2010-07-05	00:00	2010-08	00:00	MODERATE	YES	NO	RESOLVED
			ELEVATION OF CRP WITH UNKNOWN ORIGIN	2010-07-05	00:00			MILD	NO	NO	ONGOING
			WORSENING OF GENERAL CONDITION	2010-07-26	00:00			SEVERE	NO	NO	ONGOING
			ASPIRATION PNEUMONIA	2010-08-11	NK:NK	2010-08-12	NK:NK	SEVERE	YES	NO	DEATH
	046	11	VENTRICULAR AND SUPRAVENTRICULAR EXTRA SYSTOLES	2010-01-11	00:00	2010-04-07	00:00	MODERATE	NO	NO	RESOLVED
			HEMATOMA ON NOSE	2010-04-07	00:00	2010-07-07	00:00	MILD	NO	NO	RESOLVED
			UNREST	2010-11-02	00:00			MILD	NO	NO	ONGOING
			HYGROMA IN MRT	2011-01-12	10:30			MILD	NO	NO	ONGOING
			ELEVATED BACTERIA (URINE)	2011-02-07	00:00			MILD	NO	NO	ONGOING
			ELEVATED PROTEIN (URINE)	2011-02-07	00:00			MILD	NO	NO	ONGOING
	048	11	SYNCOPE	2011-08-04	00:00	2011-08-06	00:00	MILD	YES	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	043	12	DOWNFALL WITH CONTUSION AND RESULTING HAEMATOMA OF RIGHT THIGH	HOSPITALIZATION, CONCOMITANT THERAPY, OTHER	PUNCTURE OF HAEMATOMA
			ELEVATION OF CRP WITH UNKNOWN ORIGIN	NONE	
			WORSENING OF GENERAL CONDITION	STUDY DISCONTINUED PERMANENTLY	
			ASPIRATION PNEUMONIA	HOSPITALIZATION	
	046	11	VENTRICULAR AND SUPRAVENTRICULAR EXTRA SYSTOLES	NONE	
			HEMATOMA ON NOSE	NONE	
			UNREST	CONCOMITANT THERAPY	
			HYGROMA IN MRT	OTHER	CONTROLLED
			ELEVATED BACTERIA (URINE)	NONE	
			ELEVATED PROTEIN (URINE)	NONE	
	048	11	SYNCOPE	HOSPITALIZATION	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	050	21	PATIENT FEELING SICKISH	2010-11-24	06:30	2010-11-24	17:45	MILD	NO	NO	RESOLVED
			PATIENT FEELING DIZZY.	2010-11-26	06:20	2010-11-26	18:00	MILD	NO	NO	RESOLVED
			PATIENT IS FEELING NERVOUS.	2010-11-28	07:15	2010-11-28	18:30	MILD	NO	NO	RESOLVED
			TIREDNESS	2010-12-04	07:10	2010-12-04	18:10	MILD	NO	NO	RESOLVED
			NAUSEA	2010-12-05	06:30	2010-12-05	17:00	MILD	NO	NO	RESOLVED
			TIREDNESS	2010-12-06	06:50	2010-12-06	17:30	MILD	NO	NO	RESOLVED
			PATIENT IS FEELING SICKISH.	2010-12-09	07:10	2010-12-09	17:30	MILD	NO	NO	RESOLVED
			PATIENT IS FEELING SICKISH.	2010-12-11	06:50	2010-12-11	17:40	MILD	NO	NO	RESOLVED
			TIREDNESS	2010-12-13	06:30	2010-12-13	17:10	MILD	NO	NO	RESOLVED
			PATIENT IS FEELING SICKISH.	2011-01-22	07:15	2011-01-22	19:00	MILD	NO	NO	RESOLVED
			BACK PAIN	2011-01-29	06:50	2011-01-29	18:10	MILD	NO	NO	RESOLVED
			PATIENT FEELING SICKISH	2011-01-30	07:10	2011-01-30	18:00	MILD	NO	NO	RESOLVED
			DEAFNESS OF LEFT FACE, ARM AND FOOT	2011-02-02	06:55	2011-02-03	18:15	MILD	NO	NO	RESOLVED
			PAIN OF THE BONES	2011-02-14	06:30	2011-02-14	17:30	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	050	21	PATIENT FEELING SICKISH	NONE	
			PATIENT FEELING DIZZY.	NONE	
			PATIENT IS FEELING NERVOUS.	NONE	
			TIREDNESS	NONE	
			NAUSEA	NONE	
			TIREDNESS	NONE	
			PATIENT IS FEELING SICKISH.	NONE	
			PATIENT IS FEELING SICKISH.	NONE	
			TIREDNESS	NONE	
			PATIENT IS FEELING SICKISH.	NONE	
			BACK PAIN	NONE	
			PATIENT FEELING SICKISH	NONE	
			DEAFNESS OF LEFT FACE, ARM AND FOOT	NONE	
			PAIN OF THE BONES	NONE	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	050	21	TIREDNESS	2011-02-15	06:50	2011-02-16	17:30	MILD	NO	NO	RESOLVED
			PAIN OF THE JOINTS	2011-02-16	07:00	2011-02-16	17:30	MILD	NO	NO	RESOLVED
			TOOTHACHE	2011-02-17	06:55	2011-02-17	18:10	MILD	NO	NO	RESOLVED
			PAIN OF THE JOINTS	2011-02-19	07:15	2011-02-19	17:50	MILD	NO	NO	RESOLVED
			PAIN OF THE JOINTS	2011-02-23	06:50	2011-02-23	17:30	MILD	NO	NO	RESOLVED
			HOT FLASHES	2011-02-24	09:30	2011-02-24	18:10	MILD	NO	NO	RESOLVED
			PAIN OF THE JOINTS	2011-02-26	06:45	2011-02-26	18:10	MILD	NO	NO	RESOLVED
			HOT FLASHES	2011-02-27	10:00	2011-02-27	18:30	MILD	NO	NO	RESOLVED
			HOT FLASHES	2011-03-02	11:00	2011-03-02	17:50	MILD	NO	NO	RESOLVED
			PAIN OF THE JOINTS	2011-03-06	06:50	2011-03-06	17:30	MILD	NO	NO	RESOLVED
			CRAMPS IN THE HANDS	2011-03-08	07:10	2011-03-08	17:50	MILD	NO	NO	RESOLVED
			PAIN IN THE JOINTS	2011-03-08	07:10	2011-03-08	17:50	MILD	NO	NO	RESOLVED
			CRAMPS IN THE HANDS	2011-03-14	06:30	2011-03-14	18:40	MILD	NO	NO	RESOLVED
			MELANCHOLIC FEELING	2011-03-15	07:00	2011-03-15	17:45	MILD	NO	NO	RESOLVED
			PAIN OF THE BLADDER	2011-03-22	07:10	2011-03-22	18:30	MILD	NO	NO	RESOLVED
			PAIN OF THE JOINTS	2011-03-25	06:50	2011-03-25	17:50	MILD	NO	NO	RESOLVED
			PAIN OF THE BLADDER	2011-03-30	07:00	2011-03-30	18:30	MILD	NO	NO	RESOLVED
			PAIN OF THE HIP	2011-03-31	07:00	2011-03-31	19:00	MILD	NO	NO	RESOLVED
			PAIN OF THE BLADDER	2011-04-01	07:30	2011-04-01	18:10	MILD	NO	NO	RESOLVED
			PATIENT IS FEELING SICKISH.	2011-04-02	07:10	2011-04-02	18:40	MILD	NO	NO	RESOLVED
			STOMACH ACHE	2011-04-13	07:10	2011-04-13	17:30	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	050	21	TIREDNESS	NONE	
			PAIN OF THE JOINTS	NONE	
			TOOTHACHE	OTHER	VISIT TO THE DENTIST
			PAIN OF THE JOINTS	NONE	
			PAIN OF THE JOINTS	NONE	
			HOT FLASHES	NONE	
			PAIN OF THE JOINTS	NONE	
			HOT FLASHES	NONE	
			HOT FLASHES	NONE	
			PAIN OF THE JOINTS	NONE	
			CRAMPS IN THE HANDS	NONE	
			PAIN IN THE JOINTS	NONE	
			CRAMPS IN THE HANDS	NONE	
			MELANCHOLIC FEELING	NONE	
			PAIN OF THE BLADDER	OTHER	PATIENT VISITED PRACTITIONER.
			PAIN OF THE JOINTS	NONE	
			PAIN OF THE BLADDER	NONE	
			PAIN OF THE HIP	NONE	
			PAIN OF THE BLADDER	NONE	
			PATIENT IS FEELING SICKISH.	NONE	
			STOMACH ACHE	NONE	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	050	21	TIREDNESS	2011-04-20	07:00	2011-04-20	18:50	MILD	NO	NO	RESOLVED
			STOMACH ACHE	2011-04-24	06:55	2011-04-24	19:20	MILD	NO	NO	RESOLVED
			EMESIS	2011-05-05	07:00	2011-05-07	18:10	MODERATE	NO	NO	RESOLVED
			TIREDNESS	2011-05-25	06:30	2011-05-25	17:30	MILD	NO	NO	RESOLVED
			SICKISH FEELING	2011-05-29	07:00	2011-05-29	19:10	MILD	NO	NO	RESOLVED
			STOMACHACHE	2011-06-06	06:50	2011-06-09	17:30	MILD	NO	NO	RESOLVED
			SICKISH FEELING	2011-06-06	08:00	2011-06-09	20:00	MILD	NO	NO	RESOLVED
			COUGH	2011-06-07	06:50	2011-06-09	17:30	MILD	NO	NO	RESOLVED
			PAIN OF THE BLADDER, URINARY TRACT INFECTION	2011-06-09	06:50	2011-06-11	17:50	MILD	NO	NO	RESOLVED
			EARACHE	2011-06-11	07:00	2011-06-12	18:00	MILD	NO	NO	RESOLVED
			TIREDNESS	2011-06-12	08:55	2011-06-12	18:00	MILD	NO	NO	RESOLVED
			PAIN OF THE BLADDER, URINARY TRACT INFECTION	2011-06-13	07:50	2011-06-13	19:00	MILD	NO	NO	RESOLVED
			EARACHE	2011-06-14	07:30	2011-06-14	18:30	MILD	NO	NO	RESOLVED
			STOMACHACHE	2011-06-14	07:30	2011-06-15	18:30	MILD	NO	NO	RESOLVED
			PAIN OF THE BLADDER, URINARY TRACT INFECTION	2011-06-15	08:10	2011-06-15	18:30	MILD	NO	NO	RESOLVED
			EARACHE	2011-06-17	07:45	2011-06-17	18:00	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	050	21	TIREDNESS	NONE	
			STOMACH ACHE	NONE	
			EMESIS	CONCOMITANT THERAPY	
			TIREDNESS	NONE	
			SICKISH FEELING	NONE	
			STOMACHACHE	NONE	
			SICKISH FEELING	NONE	
			COUGH	NONE	
			PAIN OF THE	CONCOMITANT THERAPY	
			BLADDER, URINARY		
			TRACT INFECTION		
			EARACHE	NONE	
			TIREDNESS	NONE	
			PAIN OF THE	CONCOMITANT THERAPY	
			BLADDER, URINARY		
			TRACT INFECTION		
			EARACHE	NONE	
			STOMACHACHE	NONE	
			PAIN OF THE	CONCOMITANT THERAPY	
			BLADDER, URINARY		
			TRACT INFECTION		
			EARACHE	NONE	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	050	21	PAIN OF THE BLADDER	2011-06-18	08:10	2011-06-18	17:30	MILD	NO	NO	RESOLVED
			EARACHE	2011-06-19	07:10	2011-06-19	18:20	MILD	NO	NO	RESOLVED
			EARACHE	2011-06-21	06:45	2011-06-21	17:30	MILD	NO	NO	RESOLVED
			EARACHE	2011-06-23	07:00	2011-06-23	17:50	MILD	NO	NO	RESOLVED
			EARACHE	2011-06-27	07:05	2011-06-27	17:50	MILD	NO	NO	RESOLVED
			PERIPHERAL LOW VOLTAGE	2011-07-04	11:56	2011-10-24	09:35	MILD	NO	NO	RESOLVED
			NAUSEA	2011-07-24	06:45	2011-07-24	18:30	MILD	NO	NO	RESOLVED
			TIREDDNESS	2011-08-02	06:50	2011-08-03	17:50	MILD	NO	NO	RESOLVED
			PATIENT FEELING SICKISH	2011-08-08	06:50	2011-08-08	18:05	MILD	NO	NO	RESOLVED
			PATIENT FEELING SICKISH	2011-08-16	07:00	2011-08-17	19:00	MILD	NO	NO	RESOLVED
			PATIENT FEELING SICKISH	2011-08-21	07:00	2011-08-21	19:00	MILD	NO	NO	RESOLVED
			PATIENT FEELING SICKISH	2011-08-25	07:00	2011-08-25	19:00	MILD	NO	NO	RESOLVED
			STOMACHACHE	2011-08-27	07:00	2011-08-28	19:00	MILD	NO	NO	RESOLVED
			WEAKNESS	2011-08-30	07:00	2011-08-30	19:00	MILD	NO	NO	RESOLVED
			PATIENT FELL _ WOUND IN HER FACE	2011-08-31	07:10	2011-08-31	17:30	MILD	NO	NO	RESOLVED
			STOMACHACHE	2011-09-04	07:00	2011-09-04	19:00	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	050	21	PAIN OF THE BLADDER	NONE	
			EARACHE	NONE	
			EARACHE	NONE	
			EARACHE	NONE	
			EARACHE	NONE	
			PERIPHERAL LOW	NONE	
			VOLTAGE		
			NAUSEA	NONE	
			TIREDDNESS	NONE	
			PATIENT FEELING	NONE	
			SICKISH		
			PATIENT FEELING	NONE	
			SICKISH		
			PATIENT FEELING	NONE	
			SICKISH		
			PATIENT FEELING	NONE	
			SICKISH		
			STOMACHACHE	NONE	
			WEAKNESS	NONE	
			PATIENT FELL_ WOUND	NONE	
			IN HER FACE		
			STOMACHACHE	NONE	

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Listing 16.2.7.1: Adverse events

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				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	050	21	WEAKNESS	2011-09-05	07:00	2011-09-08	19:00	MILD	NO	NO	RESOLVED
			PATIENT FEELING SICKISH	2011-09-08	07:00	2011-09-08	19:00	MILD	NO	NO	RESOLVED
			WEAKNESS	2011-09-10	07:00	2011-09-10	19:00	MILD	NO	NO	RESOLVED
			WEAKNESS	2011-09-12	07:00	2011-09-12	19:00	MILD	NO	NO	RESOLVED
			NUMBNESS	2011-09-14	07:00	2011-09-14	19:00	MILD	NO	NO	RESOLVED
			STOMACHACHE	2011-09-19	07:00	2011-09-22	19:00	MILD	NO	NO	RESOLVED
			JOINT PAIN	2011-10-03	07:00	2011-10-04	19:00	MILD	NO	NO	RESOLVED
			PARALYSIS OF THE LEFT SIDE OF HER FACE.	2011-10-07	03:00	2011-10-07	04:00	MILD	NO	NO	RESOLVED
			JOINT PAIN	2011-10-11	07:00	2011-10-11	19:00	MILD	NO	NO	RESOLVED
			PATIENT FEELING SICKISH	2011-10-11	07:00	2011-10-11	19:00	MILD	NO	NO	RESOLVED
			JOINT PAIN	2011-10-14	07:00	2011-10-14	19:00	MILD	NO	NO	RESOLVED
			STOMACHACHE	2011-10-18	07:00	2011-10-18	19:00	MILD	NO	NO	RESOLVED
			PAIN IN JOINTS	2011-10-21	07:00	2011-10-21	19:00	MILD	NO	NO	RESOLVED
			EMESIS	2011-10-24	08:00	2011-10-28	18:00	MODERATE	NO	NO	RESOLVED
			COMMON COLD	2011-12-08	08:00			MILD	NO	NO	ONGOING
			DIARRHOEA	2011-12-08	08:00			MILD	NO	NO	ONGOING
			EMESIS	2011-12-08	08:00			MILD	NO	NO	ONGOING

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	050	21	WEAKNESS	NONE	
			PATIENT FEELING	NONE	
			SICKISH		
			WEAKNESS	NONE	
			WEAKNESS	NONE	
			NUMBNESS	NONE	
			STOMACHACHE	NONE	
			JOINT PAIN	NONE	
			PARALYSIS OF THE	NONE	
			LEFT SIDE OF HER		
			FACE.		
			JOINT PAIN	NONE	
			PATIENT FEELING	NONE	
			SICKISH		
			JOINT PAIN	NONE	
			STOMACHACHE	NONE	
			PAIN IN JOINTS	NONE	
			EMESIS	CONCOMITANT THERAPY, OTHER	EXAMINATION IN THE DEPARTMENT OF NEUROLOGY, LABORATORY
			COMMON COLD	CONCOMITANT THERAPY	
			DIARRHOEA	NONE	
			EMESIS	NONE	

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				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	052	21	HEADACHE	2010-11-01	07:00	2010-11-01	18:00	MILD	NO	NO	RESOLVED
			SPRAIN OF LEFT ANKLE	2011-02-28	12:00	2011-03-01	12:00	MILD	NO	NO	RESOLVED
	055	5	ALLERGIC REACTION	2010-03-30	09:00	2010-03-31	09:00	MILD	NO	YES	RESOLVED
			(FATIGUE, NAUSEA, DYSAESTHESIA (WHOLE BODY), PHARYNGAL STING)								
	057	1	VARIZELLA ZOSTER INFECTION	2011-04-06	08:00	2011-04-13	22:00	MODERATE	YES	NO	RESOLVED
	066	16	DIARRHOE	2010-09-18	09:00	2010-09-20	13:00	MILD	NO	YES	RESOLVED
			UNREST	2010-09-23	18:00	2011-02-03	NK:NK	MODERATE	NO	YES	RESOLVED
			DRYNESS OF MOUTH	2010-10-01	NK:NK	2011-01-06	NK:NK	MILD	NO	YES	RESOLVED
			ROOT RESECTION	2010-11-02	NK:NK	2010-11-02	NK:NK	MILD	NO	NO	RESOLVED
			AGGRESSION	2010-12-14	NK:NK	2010-12-19	NK:NK	MODERATE	NO	NO	RESOLVED WITH SEQUELAE
			WORSENING OF AGGRESSION	2010-12-20	NK:NK	2011-01-04	NK:NK	SEVERE	NO	NO	RESOLVED WITH SEQUELAE
			EMESIS	2010-12-21	NK:NK	2010-12-21	NK:NK	MILD	NO	NO	RESOLVED

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ACI-91	052	21	HEADACHE SPRAIN OF LEFT ANKLE	NONE NONE	
	055	5	ALLERGIC REACTION (FATIGUE, NAUSEA, DYSAESTHESIA (WHOLE BODY), PHARYNGAL STING)	STUDY DISCONTINUED PERMANENTLY	
	057	1	VARIZELLA ZOSTER INFECTION	HOSPITALIZATION, CONCOMITANT THERAPY	
	066	16	DIARRHOE UNREST DRYNESS OF MOUTH ROOT RESECTION AGGRESSION	NONE CONCOMITANT THERAPY NONE CONCOMITANT THERAPY, OTHER CONCOMITANT THERAPY	SURGERY
			WORSENING OF AGGRESSION EMESIS	NONE	

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	066	16	WORSENING OF AGGRESSION	2011-01-05	NK:NK	2011-02-03	NK:NK	SEVERE	YES	NO	RESOLVED WITH SEQUELAE
			AGGRESSION	2011-02-04	NK:NK			MILD	NO	NO	ONGOING
	067	16	HEADACHE	2010-11-19	08:30	2011-01-03	NK:NK	MODERATE	NO	YES	RESOLVED
			NAUSEA	2010-11-19	08:30	2011-01-01	NK:NK	MODERATE	NO	YES	RESOLVED
			BAD DREAMS	2010-11-19	20:30	2011-01-03	NK:NK	MODERATE	NO	YES	RESOLVED
			XEROSTOMIA	2010-11-20	NK:NK	2010-12-06	NK:NK	MODERATE	NO	YES	RESOLVED
			VOMITING	2010-11-29	NK:NK	2011-01-01	NK:NK	MILD	NO	YES	RESOLVED
	071	18	CATARACT RIGHT	2010-12	NK:NK	2010-12-15	NK:NK	MILD	NO	NO	RESOLVED WITH SEQUELAE
			DIARRHOEA	2010-11-14	NK:NK	2010-11-16	NK:NK	MILD	NO	NO	RESOLVED
			CICATRICE AFTER KATARACT EXCISION	2011-02-03	NK:NK	2011-02-07	NK:NK	MILD	NO	NO	RESOLVED WITH SEQUELAE
			HIGHT GAMMA-GT	2011-02-03	10:07	2011-04-12	10:10	MODERATE	NO	YES	RESOLVED
			SURGERY TO REMOVE CICATRICE AFTER KATARACT EXCISION	2011-02-07	NK:NK	2011-02-09	NK:NK	MILD	YES	NO	RESOLVED WITH SEQUELAE
			WORSENING HYPERTENSION	2011-02-13	NK:NK	2011-02-13	NK:NK	MODERATE	NO	NO	RESOLVED

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	066	16	WORSENING OF AGGRESSION	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
			AGGRESSION	CONCOMITANT THERAPY	
	067	16	HEADACHE	STUDY DISCONTINUED PERMANENTLY	
			NAUSEA	STUDY DISCONTINUED PERMANENTLY	
			BAD DREAMS	STUDY DISCONTINUED PERMANENTLY	
			XEROSTOMIA	STUDY DISCONTINUED PERMANENTLY	
			VOMITING	STUDY DISCONTINUED PERMANENTLY	
	071	18	CATARACT RIGHT	OTHER	AMULANT OPERATION
			DIARRHOEA	NONE	
			CICATRICE AFTER KATARACT EXCISION	OTHER	NEW OPERATION PLANNED
			HIGHT GAMMA-GT	NONE	
			SURGERY TO REMOVE CICATRICE AFTER KATARACT EXCISION	HOSPITALIZATION	
			WORSENING HYPERTENSION	CONCOMITANT THERAPY	

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	071	18	COMEDO IN FACE WORSENING HYPERTENSION	2011-03-01	NK:NK	2011-05-04	NK:NK	MODERATE	NO	NO	RESOLVED
				2011-11-17	11:45	2011-12-05	12:10	MILD	NO	NO	RESOLVED
	080	13	PSYCHOSIS (DELUSIONS AND HALLUZINATIONS) WORSENING OF DEPRESSION WORSENING OF ORIENTATION NOTCHES IN THE TONGUE INCREASED CREATININE LEUCOZYTEN IN URINE FURTHER WORSENING OF ORIENTATION WORSENING PYCHOSIS (DELUSIONS AND HALLUZINATIONS) OBSTIPATION	2010-12	NK:NK	2011-02-26	NK:NK	MILD	NO	YES	RESOLVED WITH SEQUELAE
				2010-12	NK:NK	2011-05	NK:NK	MODERATE	NO	NO	RESOLVED
				2010-12	NK:NK			MODERATE	NO	NO	ONGOING
				2010-11-24	NK:NK			MODERATE	NO	YES	ONGOING
				2010-12-29	NK:NK	2011-02-09	NK:NK	MODERATE	NO	YES	RESOLVED
				2010-12-29	NK:NK	2011-02-09	NK:NK	MILD	NO	NO	RESOLVED
				2011-02-26	NK:NK	2011-05	NK:NK	SEVERE	NO	YES	RESOLVED
				2011-02-26	NK:NK	2011-05	NK:NK	SEVERE	YES	YES	RESOLVED
				2011-02-27	NK:NK			MILD	NO	NO	ONGOING

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	071	18	COMEDO IN FACE	NONE	
			WORSENING HYPERTENSION	NONE	
	080	13	PSYCHOSIS	NONE	
			(DELUSIONS AND HALLUZINATIONS)		
			WORSENING OF DEPRESSION	CONCOMITANT THERAPY	
			WORSENING OF ORIENTATION	CONCOMITANT THERAPY, OTHER	EXTRA VISIT 29-DEC-2010
			NOTCHES IN THE TONGUE	NONE	
			INCREASED CREATININE	NONE	
			LEUCOZYTEN IN URINE	NONE	
			FURTHER WORSENING OF ORIENTATION	STUDY DISCONTINUED PERMANENTLY	
			WORSENING PYCHOSIS (DELUSIONS AND HALLUZINATIONS)	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
			OBSTIPATION	CONCOMITANT THERAPY	

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				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
ACI-91	081	17	FALL, SUBDURAL HEMATOMA	2011-09-05	14:00	2011-09-20	09:00	MILD	YES	NO	RESOLVED
	087	16	WORSENING OF DEMENTIA	2011-01-01	NK:NK			MODERATE	NO	YES	ONGOING
			DIARRHOE	2011-05-01	NK:NK			MODERATE	NO	NO	ONGOING
			INCONTINENZ INDIFFERENT	2011-11-01	NK:NK			MILD	NO	NO	ONGOING
	089	5	VASOVAGAL SYNCOPE	2011-01-06	17:20	2011-01-06	17:22	MILD	NO	NO	RESOLVED
			AV BLOCK FIRST DEGREE	2011-02-07	11:30	2011-02-16	10:35	MILD	NO	NO	RESOLVED
			URINARY TRACT INFECTION	2011-11-14	08:00	2011-11-21	NK:NK	MILD	NO	NO	RESOLVED
	097	12	HEMATOMA RIGHT THIGH	2011-02-04	00:00			MILD	NO	NO	ONGOING
			BRONCHOPULMONAL FEBRILE INFEKTION	2011-02-16	00:00			MODERATE	YES	NO	ONGOING
	Placebo	001	1	DIZZINESS AND NAUSEA	2009-04-11	08:00	2009-04-13	08:00	MILD	NO	YES
NAUSEA				2009-05-16	21:00	2009-05-17	08:00	MILD	NO	YES	RESOLVED
HYPERTENSION				2009-06-18	08:00			MILD	NO	NO	ONGOING

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
ACI-91	081	17	FALL, SUBDURAL HEMATOMA	OTHER	MRI, SUBDURAL HEMATOMA RESOLVED
	087	16	WORSENING OF DEMENTIA	CONCOMITANT THERAPY	
			DIARRHOE	NONE	
			INCONTINENZ	NONE	
			INDIFFERENT		
	089	5	VASOVAGAL SYNCOPE	NONE	
			AV BLOCK FIRST DEGREE	NONE	
			URINARY TRACT INFECTION	OTHER	REFERRAL TO GP FOR FOLLOW-UP
	097	12	HEMATOMA RIGHT THIGH BRONCHOPULMONAL FEBRILE INFEKTION	NONE HOSPITALIZATION, CONCOMITANT THERAPY	
Placebo	001	1	DIZZINESS AND NAUSEA	NONE	
			NAUSEA	NONE	
			HYPERTENSION	CONCOMITANT THERAPY	

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	001	1	INTERMITTENT NERVOUS STOMACH WITH DIZINESS AND WEAKNESS	2009-07-25	08:30			MILD	NO	NO	ONGOING
			ESSENTIAL TREMOR	2009-12-10	NK:NK			MILD	NO	NO	ONGOING
			URINARY TRACT INFECTION	2010-02-05	08:00	2010-02-10	20:00	MILD	NO	NO	RESOLVED
	003	1	NAUSEA AND EMESIS DUE TO RIVASTIGMIN	2009-07-03	08:50	2009-07-03	17:30	SEVERE	NO	NO	RESOLVED
			WORSENING OF DEPRESSION	2009-10-01	08:00	2009-11-01	08:00	MILD	NO	NO	RESOLVED
	011	1	RIGHT BUNDLE BRANCH BLOCK	2010-05-06	12:47			MILD	NO	NO	ONGOING
			URINARY TRACT INFECTION	2010-12-27	NK:NK	2010-12-31	NK:NK	MILD	NO	NO	RESOLVED
	016	4	DIZZINESS AND NAUSEA, BLURRED VISION	2010-04-16	00:00	2010-04-22	00:00	MODERATE	NO	NO	RESOLVED
			DIZZINESS	2010-05-20	06:50	2010-05-20	18:50	MILD	NO	NO	RESOLVED

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
Placebo	001	1	INTERMITTENT NERVOUS STOMACH WITH DIZINESS AND WEAKNESS ESSENTIAL TREMOR URINARY TRACT INFECTION	OTHER CONCOMITANT THERAPY CONCOMITANT THERAPY	CHECK BY THE INTERNIST, NO PATHOLOGICAL RESULT
	003	1	NAUSEA AND EMESIS DUE TO RIVASTIGMIN WORSENING OF DEPRESSION	IMP DISCONTINUED AND RESTARTED, CONCOMITANT THERAPY CONCOMITANT THERAPY	
	011	1	RIGHT BUNDLE BRANCH BLOCK URINARY TRACT INFECTION	OTHER CONCOMITANT THERAPY	GENERAL PRACTICIONER INFORMED
	016	4	DIZZINESS AND NAUSEA, BLURRED VISION DIZZINESS	OTHER NONE	DONEPEZIL 10 MG AFTER LUNCH INSTEAD OF IN THE MORNING

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				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	016	4	EPILEPTIC TYPICAL SPIKES AND SERIES OF SPIKES ON EEG, DURING THE NEUROPSYCHOLOGICAL EXAMINATION PROBABLE ABSENCE FOR FEW SECONDS.	2011-02-28	11:30			MILD	NO	NO	ONGOING
	024	4	CATARACT SURGERY LEFT EYE	2010-11-30	09:00	2010-11-30	12:00	MILD	NO	NO	RESOLVED
			DENTAL INFECTION	2011-01-28	09:00	2011-02-01	21:00	MILD	NO	NO	RESOLVED

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Placebo	016	4	EPILEPTIC TYPICAL SPIKES AND SERIES OF SPIKES ON EEG, DURING THE NEUROPSYCHOLOGICAL EXAMINATION PROBABLE ABSENCE FOR FEW SECONDS.	CONCOMITANT THERAPY	
	024	4	CATARACT SURGERY LEFT EYE DENTAL INFECTION	OTHER OTHER	OUT PATIENT MINIMAL SURGERY ANTIBIOTIC THERAPY PO. (SEE CONCOMITANT MEDICATION)

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				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	024	4	NEW ECG FINDINGS (WITHOUT CLINICAL SYMPTOMS): VENTRICULAR EXTRA SYSTOLES IN THE ECG OF 08.08.2011 IN ADDITION TO THE KNOWN COMPLETE RIGHT BUNDLE BRANCH BLOCK	2011-08-08	13:59			MILD	NO		
	028	20	MONOCYTOSIS	2011-02-23	NK:NK			MILD	NO	NO	ONGOING
			URINARY TRACT INFECTION	2011-02-23	NK:NK	2011-03-10	NK:NK	MILD	NO	NO	RESOLVED
			COUGH-PNEUMONIA	2011-03-02	NK:NK	2011-03-17	NK:NK	MODERATE	YES	NO	RESOLVED
	029	8	PAIN IN THE THENAR	2010-01-28	17:45	2010-01-29	12:00	MILD	NO	NO	RESOLVED
			HEADACHE (AFTER LP)	2010-01-29	10:00	2010-01-29	15:00	SEVERE	NO	NO	RESOLVED
			RECURRENT ELEVATED LEUCOCYTES IN URIN	2010-01-29	15:00			MILD	NO	NO	ONGOING
			CRAMP IN THE CALF	2010-01-29	21:00	2010-01-29	NK:NK	MILD	NO	NO	RESOLVED

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Placebo	024	4	NEW ECG FINDINGS (WITHOUT CLINICAL SYMPTOMS): VENTRICULAR EXTRA SYSTOLES IN THE ECG OF 08.08.2011 IN ADDITION TO THE KNOWN COMPLETE RIGHT BUNDLE BRANCH BLOCK	OTHER	PATIENT HAS TO PERFORM CARDIOLOGIC EXAMINATIONS (ECG, ULTRASOUND, ERGOMETRIC ECG, 24H ECG) ACCORDING TO THE RECOMMENDATION OF OUR CONSULTING CARDIOLOGIST.
	028	20	MONOCYTOSIS URINARY TRACT INFECTION COUGH-PNEUMONIA	OTHER CONCOMITANT THERAPY HOSPITALIZATION, CONCOMITANT THERAPY	BLOOD COUNT TO HÄMATOLOGY DEPARTMENT
	029	8	PAIN IN THE THENAR HEADACHE (AFTER LP) RECURRENT ELEVATED LEUCOCYTES IN URIN CRAMP IN THE CALF	CONCOMITANT THERAPY NONE NONE CONCOMITANT THERAPY	

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				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	029	8	SHOULDER AND NECK PAIN	2010-01-30	11:00	2010-01-30	NK:NK	MILD	NO	NO	RESOLVED
			RINGING IN THE EARS	2010-02-01	NK:NK	2010-02-01	NK:NK	MILD	NO	NO	RESOLVED
			GASTRITIS	2010-02-03	NK:NK	2010-02-10	NK:NK	MODERATE	NO	NO	RESOLVED
			VOMITING	2010-02-03	01:30	2010-02-10	NK:NK	MODERATE	NO	NO	RESOLVED
			URINARY TRACT INFECTION	2010-07-05	10:30	2010-08-13	NK:NK	SEVERE	NO	NO	RESOLVED
			FEELING OF FULLNESS	2010-08-24	19:30	2010-08-24	22:00	MILD	NO	NO	RESOLVED
			URINARY TRACT INFECTION	2010-09-30	11:00	2010-10-06	NK:NK	MILD	NO	NO	RESOLVED
			SLIGHT ELEVATED EPITHELIAL CELLS IN URINE	2011-02-01	10:45			MILD	NO	NO	ONGOING
			SLIGHT ELEVATED NEUTROPHILE GRANULOCYTES	2011-02-23	NK:NK			MILD	NO	NO	ONGOING
			URINARY TRACT INFECTION	2011-02-23	NK:NK			MILD	NO	NO	ONGOING
	031	8	LEFT ARM PRICKLING	2010-07	NK:NK			MILD	NO	NO	ONGOING
			RECURRENT PAIN IN THE LOWER BACK	2010-05-20	18:00	2010-05-22	18:00	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
Placebo	029	8	SHOULDER AND NECK PAIN	CONCOMITANT THERAPY	
			RINGING IN THE EARS	CONCOMITANT THERAPY	
			GASTRITIS	CONCOMITANT THERAPY	
			VOMITING	CONCOMITANT THERAPY	
			URINARY TRACT INFECTION	CONCOMITANT THERAPY	
			FEELING OF FULLNESS	CONCOMITANT THERAPY	
			URINARY TRACT INFECTION	CONCOMITANT THERAPY	
			SLIGHT ELEVATED EPITHELIAL CELLS IN URINE	NONE	
			SLIGHT ELEVATED NEUTROPHILE GRANULOCYTES	NONE	
			URINARY TRACT INFECTION	NONE	
	031	8	LEFT ARM PRICKLING	NONE	
			RECURRENT PAIN IN THE LOWER BACK	NONE	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	031	8	SCAPULA PAIN LEFT	2010-10-26	06:00	2010-11-30	NK:NK	MODERATE	NO	NO	RESOLVED
			DISORIENTATION	2011-05-18	NK:NK	2011-06-06	NK:NK	MILD	NO	NO	RESOLVED
			INSOMNIA	2011-05-18	NK:NK			MODERATE	NO	NO	ONGOING
	034	9	NAUSEA	2010-03-26	00:00	2010-03-26	00:00	MILD	NO	NO	RESOLVED
			GENERAL MALAISE	2010-04-29	00:00	2010-04-29	00:00	MILD	NO	YES	RESOLVED
	041	12	GASTRITIS	2009-10-17	14:00	2009-11-03	00:00	MILD	NO	NO	RESOLVED
			ARTERIAL HYPERTENSION	2010-01-11	00:00			MILD	NO	NO	ONGOING
	045	11	RUSH LEFT LEG	2009-12-21	00:00			MILD	NO	NO	ONGOING
			ORTHOSTATIC SYNCOPE	2010-01-30	07:30	2010-02-04	12:00	MODERATE	NO	NO	RESOLVED
			WITH GASTROINTESTINAL INFECTION								
			LIPOMA BACK LEFT	2010-02-10	00:00			MILD	NO	NO	ONGOING
			ABLATION OF VITREOUS BODY	2010-05-06	00:00	2010-05-17	00:00	MILD	NO	NO	RESOLVED
	049	21	RECURRING URINARY TRACT INFECTION	2010-10-24	00:00	2010-11-21	23:59	MILD	NO	NO	RESOLVED

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
Placebo	031	8	SCAPULA PAIN LEFT DISORIENTATION INSOMNIA	CONCOMITANT THERAPY, OTHER NONE CONCOMITANT THERAPY	PHYSIOTHERAPY
	034	9	NAUSEA GENERAL MALAISE	NONE NONE	
	041	12	GASTRITIS ARTERIAL HYPERTENSION	CONCOMITANT THERAPY CONCOMITANT THERAPY	
	045	11	RUSH LEFT LEG ORTHOSTATIC SYNCOPE WITH GASTROINTESTINAL INFECTION LIPOMA BACK LEFT ABLATION OF VITREOUS BODY	NONE IMP DISCONTINUED AND RESTARTED NONE IMP DISCONTINUED AND RESTARTED	
	049	21	RECURRING URINARY TRACT INFECTION	CONCOMITANT THERAPY	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	049	21	AGGRESSIVE BEHAVIOUR	2010-11-01	08:00	2010-11-04	18:30	MILD	NO	NO	RESOLVED
			AGGRESSIVE BEHAVIOUR	2010-11-08	07:30	2010-11-08	18:30	MILD	NO	NO	RESOLVED
			BURN OF THE LEFT HAND	2010-11-19	00:00	2010-11-19	23:59	MILD	NO	NO	RESOLVED
			AGGRESSIVE BEHAVIOUR	2010-12-18	09:00	2010-12-18	19:30	MILD	NO	NO	RESOLVED
			AGGRESSIVE BEHAVIOUR	2011-01-13	07:30	2011-01-13	17:00	MILD	NO	NO	RESOLVED
			AGGRESSIVE BEHAVIOUR	2011-01-26	16:00	2011-01-26	21:00	MILD	NO	NO	RESOLVED
			COLD	2011-01-30	07:30	2011-01-30	18:00	MILD	NO	NO	RESOLVED
			AGGRESSIVE BEHAVIOR	2011-02-03	07:30	2011-02-06	18:00	MILD	NO	NO	RESOLVED
			LOSS OF APPETITE	2011-03-18	08:00	2011-03-19	18:00	MILD	NO	NO	RESOLVED
			EMESIS	2011-05-08	07:00	2011-05-08	10:00	MILD	NO	NO	RESOLVED
			NAUSEA	2011-05-08	07:00	2011-05-08	10:00	MILD	NO	NO	RESOLVED
			APATHY	2011-05-08	08:00	2011-05-09	20:00	MILD	NO	NO	RESOLVED
			VITAMIN D3 DEFICIENCY	2011-05-27	10:47			MILD	NO	NO	ONGOING
			LOSS OF APPETITE	2011-09-01	07:30	2011-09-05	18:00	MILD	NO	NO	RESOLVED
			INCREASING PSYCHOPATHOLOGICAL SYMPTOMS	2011-09-06	00:00			SEVERE	YES	NO	ONGOING
			POTASSIUM DEFICIENCY	2011-09-06	08:00	2011-10-14	23:59	MILD	NO	NO	RESOLVED
			VITAMIN B12 DEFICIENCY	2011-09-06	08:00			MILD	NO	NO	ONGOING

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
Placebo	049	21	AGGRESSIVE BEHAVIOUR	NONE	
			AGGRESSIVE BEHAVIOUR	NONE	
			BURN OF THE LEFT HAND	OTHER	VISIT AT DEPARTMENT OF DERMATOLOGY
			AGGRESSIVE BEHAVIOUR	NONE	
			AGGRESSIVE BEHAVIOUR	NONE	
			AGGRESSIVE BEHAVIOUR	NONE	
			COLD	CONCOMITANT THERAPY	
			AGGRESSIVE BEHAVIOR	NONE	
			LOSS OF APPETITE	NONE	
			EMESIS	NONE	
			NAUSEA	NONE	
			APATHY	NONE	
			VITAMIN D3 DEFICIENCY	CONCOMITANT THERAPY	
			LOSS OF APPETITE	NONE	
			INCREASING	HOSPITALIZATION, STUDY	
			PSYCHOPATHOLOGICAL SYMPTOMS	DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
			POTASSIUM DEFICIENCY	CONCOMITANT THERAPY	
			VITAMIN B12 DEFICIENCY	CONCOMITANT THERAPY	

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	049	21	PELVIC VEIN THROMBOSIS	2011-09-10	08:00	2011-09-19	18:00	SEVERE	YES	NO	RESOLVED
	051	21	ANXIETY	2011-03-02	20:00	2011-03-03	08:00	MILD	NO	NO	RESOLVED
			ANXIETY	2011-04-12	07:00	2011-07-05	19:00	MILD	NO	NO	RESOLVED
			SLOW R WAVE PROGRESSION	2011-04-12	13:37	2011-07-05	13:47	MILD	NO	NO	RESOLVED
	056	5	WORSENING OF CHRONIC BACK PAIN DUE TO SPINAL CANAL STENOSIS	2010-05-03	00:00	2010-07-05	00:00	MODERATE	YES	NO	RESOLVED
	058	1	HIGH BLOOD PRESSURE	2011-03-23	NK:NK			MILD	NO	NO	ONGOING
			COLD	2011-06-04	08:00	2011-06-10	22:00	MILD	NO	NO	RESOLVED
			SINUSITIS	2011-10-13	08:00	2011-10-16	22:00	MILD	NO	NO	RESOLVED
			BACTERIURIA	2011-12-06	08:00	2011-12-13	10:00	MILD	NO	NO	RESOLVED
			COGNITION WORSENING	2011-12-13	08:00	2012-01-10	08:00	MILD	NO	YES	RESOLVED WITH SEQUELAE
	059	1	INFLUENZAL INFECTION	2011-02-13	NK:NK	2011-02-15	NK:NK	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
Placebo	049	21	PELVIC VEIN THROMBOSIS	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
	051	21	ANXIETY ANXIETY SLOW R WAVE PROGRESSION	NONE NONE NONE	
	056	5	WORSENING OF CHRONIC BACK PAIN DUE TO SPINAL CANAL STENOSIS	HOSPITALIZATION, CONCOMITANT THERAPY, OTHER	SURGERY OF SPINAL CANAL STENOSIS
	058	1	HIGH BLOOD PRESSURE COLD SINUSITIS BACTERIURIA COGNITION WORSENING	CONCOMITANT THERAPY CONCOMITANT THERAPY CONCOMITANT THERAPY NONE NONE	
	059	1	INFLUENZAL INFECTION	CONCOMITANT THERAPY	

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Listing 16.2.7.1: Adverse events

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13FEB2013

Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	059	1	HERPES ZOSTER	2011-05-30	08:00	2011-06-09	22:00	MODERATE	NO	NO	RESOLVED
			HEADACHE	2011-05-31	08:00	2011-05-31	22:00	MILD	NO	NO	RESOLVED
			LUMBAGO	2011-09-13	08:00	2011-09-17	22:00	MILD	NO	NO	RESOLVED
			DEPRESSION DUE TO AD	2011-08	08:00			MILD	NO	NO	ONGOING
	065	16	OPSTIPATION	2011-04	NK:NK			MILD	NO	NO	ONGOING
			SENSATION OF HEAT IN HEAD AND UPPER BODY	2010-11-10	NK:NK	2010-12-12	NK:NK	MILD	NO	NO	RESOLVED
			PAIN IN BOTH CALFS	2011-01-16	NK:NK			MILD	NO	NO	ONGOING
			RELAPSE OF ALCOHOL DEPENDENCE	2011-03-16	NK:NK	2011-04-14	NK:NK	MODERATE	YES	NO	RESOLVED
	068	16	WORSENING OF DEMENTIA	2011-03-16	NK:NK	2011-04-14	NK:NK	MODERATE	YES	NO	RESOLVED
			MICROHAEMATURIA	2011-02-10	NK:NK	2011-05-03	NK:NK	MILD	NO	NO	RESOLVED
			LOSS OF WEIGHT	2011-08-10	NK:NK			MODERATE	NO	NO	ONGOING
			INCONTINENCE	2011-10-01	NK:NK			MODERATE	NO	NO	ONGOING
			FACE INJURY DUE TO FALL	2011-11-14	NK:NK	2011-11-14	NK:NK	MILD	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
Placebo	059	1	HERPES ZOSTER	CONCOMITANT THERAPY	
			HEADACHE	CONCOMITANT THERAPY	
			LUMBAGO	CONCOMITANT THERAPY	
			DEPRESSION DUE TO AD	CONCOMITANT THERAPY	
	065	16	OPSTIPATION	CONCOMITANT THERAPY	
			SENSATION OF HEAT	NONE	
			IN HEAD AND UPPER		
			BODY		
			PAIN IN BOTH CALFS	NONE	
			RELAPSE OF ALCOHOL	HOSPITALIZATION, STUDY	
			DEPENDENCE	DISCONTINUED PERMANENTLY,	
				CONCOMITANT THERAPY	
			WORSENING OF	HOSPITALIZATION, CONCOMITANT	
			DEMENTIA	THERAPY	
	068	16	MICROHAEMATURIA	NONE	
			LOSS OF WEIGHT	NONE	
			INCONTINENCE	NONE	
			FACE INJURY DUE TO	NONE	
			FALL		

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Listing 16.2.7.1: Adverse events

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Treat- ment	Random No.	Site ID	Adverse event	Start of AE		Stop of AE		Severity	Ser- ious	Relation to IMP	Outcome
				Date YYYY-MM-DD	Time	Date YYYY-MM-DD	Time				
Placebo	079	13	COMON COLD DIARRHOE	2010-11-05	NK:NK	2010-11-30	NK:NK	MILD	NO	NO	RESOLVED
				2011-07-16	NK:NK	2011-07-17	NK:NK	MILD	NO	NO	RESOLVED
	086	21	COMMON COLD INTERMITTENT SINUS ARRHYTHMIA LEFT ANTERIOR HEMIBLOCK PLANNED SURGERY OF CATARACTA CORTICONUCLEARIS SENILIS	2010-12-02	00:00	2010-12-03	00:00	MILD	NO	NO	RESOLVED
				2011-04-12	12:04	2011-07-05	12:02	MILD	NO	NO	RESOLVED
				2011-10-25	11:49			MILD	NO	NO	ONGOING
				2011-11-02	07:30	2011-11-05	19:30	SEVERE	NO	NO	RESOLVED
	088	16	AGRESSION WORSENING OF AGRESSION AGITATION PROGRESSION OF ALZHEIMERS DISEASE COMMON COLD SYNCOPE	2010-12-20	NK:NK	2011-02-10	NK:NK	MILD	NO	NO	RESOLVED
				2011-02-10	NK:NK	2011-07-01	NK:NK	MODERATE	NO	NO	RESOLVED
				2011-05-04	NK:NK			MILD	NO	NO	ONGOING
				2011-07-26	NK:NK	2011-08-23	NK:NK	MILD	YES	YES	RESOLVED WITH SEQUELAE
				2012-01-04	NK:NK	2012-01-14	NK:NK	MODERATE	NO	NO	RESOLVED
				2012-01-13	NK:NK	2012-01-13	NK:NK	MODERATE	NO	NO	RESOLVED

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Listing 16.2.7.1: Adverse events

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13FEB2013

Treat- ment	Random No.	Site ID	Adverse event	Action taken	Other action
Placebo	079	13	COMON COLD DIARRHOE	CONCOMITANT THERAPY NONE	
	086	21	COMMON COLD INTERMITTENT SINUS ARRHYTHMIA	CONCOMITANT THERAPY NONE	
			LEFT ANTERIOR HEMIBLOCK	NONE	
			PLANNED SURGERY OF CATARACTA CORTICONUCLEARIS SENILIS		PLANNED SURGERY AND PLANNED HOSPITALIZATION
	088	16	AGRESSION WORSENING OF AGRESSION	CONCOMITANT THERAPY CONCOMITANT THERAPY	
			AGITATION PROGRESSION OF ALZHEIMERS DISEASE	CONCOMITANT THERAPY HOSPITALIZATION, CONCOMITANT THERAPY	
			COMMON COLD SYNCOPE	NONE NONE	

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Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	ANEMIA, UNSPECIFIED	ANAEMIA OF UNKNOWN ORIGIN
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MONOCYTOSIS	MONOCYTOSIS	MONOCYTOSIS
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	AV BLOCK FIRST DEGREE	AV BLOCK FIRST DEGREE
CARDIAC DISORDERS	BRADYCARDIA	BRADYCARDIA	BRADYCARDIA
CARDIAC DISORDERS	SINUS ARRHYTHMIA	SINUS ARRHYTHMIA	INTERMITTENT SINUS ARRHYTHMIA
CARDIAC DISORDERS	BUNDLE BRANCH BLOCK LEFT	LEFT ANTERIOR HEMIBLOCK	LEFT ANTERIOR HEMIBLOCK
CARDIAC DISORDERS	VENTRICULAR EXTRASYSTOLES	VENTRICULAR EXTRASYSTOLES	NEW ECG FINDINGS (WITHOUT CLINICAL SYMPTOMS) : VENTRICULAR EXTRA SYSTOLES IN THE ECG OF 08.08.2011 IN ADDITION TO THE KNOWN COMPLETE RIGHT BUNDLE BRANCH BLOCK
CARDIAC DISORDERS	BUNDLE BRANCH BLOCK RIGHT	RIGHT BUNDLE BRANCH BLOCK	RIGHT BUNDLE BRANCH BLOCK
CARDIAC DISORDERS	EXTRASYSTOLES	EXTRASYSTOLES	VENTRICULAR AND SUPRAVENTRICULAR EXTRA SYSTOLES
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	CYSTIC LYMPHANGIOMA	HYGROMA CYSTIC	HYGROMA IN MRT
EAR AND LABYRINTH DISORDERS	EAR PAIN	EARACHE	EARACHE
EAR AND LABYRINTH DISORDERS	TINNITUS	RINGING IN EARS	RINGING IN THE EARS
EAR AND LABYRINTH DISORDERS	VERTIGO	VERTIGO NEC	VERTIGO
EYE DISORDERS	VITREOUS DISORDER	DISORDERS OF VITREOUS BODY	ABLATION OF VITREOUS BODY
EYE DISORDERS	CATARACT	CATARACT (RIGHT)	CATARACT RIGHT
GASTROINTESTINAL DISORDERS	DIARRHOEA	DIARRHEA	DIARRHEA
GASTROINTESTINAL DISORDERS	DIARRHOEA	DIARRHOEA	DIARRHOE

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
GASTROINTESTINAL DISORDERS	DIARRHOEA	DIARRHOEA	DIARRHOEA
GASTROINTESTINAL DISORDERS	DRY MOUTH	DRY MOUTH	DRYNESS OF MOUTH
GASTROINTESTINAL DISORDERS	VOMITING	EMESIS	EMESIS
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	ABDOMINAL FULLNESS	FEELING OF FULLNESS
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	GASTRIC PAIN	GASTRAL PAIN
GASTROINTESTINAL DISORDERS	GASTRITIS	GASTRITIS	GASTRITIS
GASTROINTESTINAL DISORDERS	ABDOMINAL DISCOMFORT	IRRITABLE STOMACH	INTERMITTENT NERVOUS STOMACH WITH DIZZINESS AND WEAKNESS
GASTROINTESTINAL DISORDERS	NAUSEA	NAUSEA	NAUSEA
GASTROINTESTINAL DISORDERS	VOMITING	NAUSEA AND VOMITING	NAUSEA AND VOMITING
GASTROINTESTINAL DISORDERS	TONGUE DISORDER	TONGUE DISORDER	NOTCHES IN THE TONGUE
GASTROINTESTINAL DISORDERS	CONSTIPATION	OBSTIPATION	OBSTIPATION
GASTROINTESTINAL DISORDERS	CONSTIPATION	OBSTIPATION	OPSTIPATION
GASTROINTESTINAL DISORDERS	DRY MOUTH	XEROSTOMIA	RECURRENT XEROSTOMIA
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	STOMACH PAIN	STOMACH ACHE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	STOMACH PAIN	STOMACHACHE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	STOMACH PAIN	STOMACHE PAIN
GASTROINTESTINAL DISORDERS	TOOTHACHE	TOOTHACHE	TOOTHACHE
GASTROINTESTINAL DISORDERS	VOMITING	VOMITING	VOMITING
GASTROINTESTINAL DISORDERS	DRY MOUTH	XEROSTOMIA	XEROSTOMIA
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ADVERSE DRUG REACTION	DRUG SIDE EFFECT	DRY COUGH DUE TO RAMIPRIL
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	FATIGUE	FATIGUE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISOMFORT	GENERAL DISCOMFORT	GENERAL DISCOMFORT OBSERVED BY SPOUSE

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	GENERAL MALAISE	GENERAL MALAISE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	TIREDNESS	INTERMITTEND TIREDNESS
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ADVERSE DRUG REACTION	DRUG SIDE EFFECT	NAUSEA AND EMESIS DUE TO RIVASTIGMIN
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	FEELING SICK	PATIENT FEELING SICKISH
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	FEELING SICK	PATIENT IS FEELING SICKISH.
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	FEVER	PYREXIA OF UP TO 40 °C
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	CHEST PAIN NEC	RECURRENT PAIN IN THE CHEST LEFT SIDE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING HOT	SENSATION OF HEAT	SENSATION OF HEAT IN HEAD AND UPPER BODY
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	FEELING SICK	SICKISH FEELING

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	TIREDNESS	TIREDNESS
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	WEAKNESS	WEAKNESS
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GENERAL PHYSICAL HEALTH DETERIORATION	REDUCED GENERAL CONDITION	WORSENING OF GENERAL CONDITION
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	ALLERGIC REACTION	ALLERGIC REACTION (FATIGUE, NAUSEA, DYSAESTHESIA (WHOLE BODY), PHARYNGAL STING)
INFECTIONS AND INFESTATIONS	BACTERIURIA	BACTERIURIA	BACTERIURIA
INFECTIONS AND INFESTATIONS	CYSTITIS	BLADDER INFECTION	BLADDER INFECTION
INFECTIONS AND INFESTATIONS	BRONCHITIS	ACUTE BRONCHITIS	BRONCHOPULMONAL FEBRILE INFEKTION
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	COLD	COLD
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	COMMON COLD	COMMON COLD
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	COMMON COLD	COMON COLD
INFECTIONS AND INFESTATIONS	PNEUMONIA	PNEUMONIA	COUGH-PNEUMONIA
INFECTIONS AND INFESTATIONS	TOOTH INFECTION	TOOTH INFECTION	DENTAL INFECTION
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	SKIN FUNGAL INFECTION NOS	FUNGAL SKIN INFECTION
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	HERPES ZOSTER	HERPES ZOSTER
INFECTIONS AND INFESTATIONS	INFLUENZA	INFLUENZA	INFLUENZAL INFECTION
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL INFECTION	GASTROINTESTINAL INFECTION	ORTHOSTATIC SYNCOPE WITH GASTROINTESTINAL INFECTION
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	URINARY TRACT INFECTION	PAIN OF THE BLADDER, URINARY TRACT INFECTION
INFECTIONS AND INFESTATIONS	PNEUMONIA	PNEUMONIA	PNEUMONIA

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	URINARY TRACT INFECTION	RECURRING URINARY TRACT INFECTION
INFECTIONS AND INFESTATIONS	SINUSITIS	SINUSITIS	SINUSITIS
INFECTIONS AND INFESTATIONS	TINEA PEDIS	TINEA PEDIS	TINEA PEDIS
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	URINARY TRACT INFECTION	URINARY TRACT INFECTION
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	VARICELLA ZOSTER	VARIZELLA ZOSTER INFECTION
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	THERMAL BURN	BURN OF UNSPECIFIED DEGREE OF UNSPECIFIED SITE OF HAND	BURN OF THE LEFT HAND
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CORNEAL SCAR	CICATRIX CORNEAL	CICATRICE AFTER KATARACT EXCISION
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	UPPER LIMB FRACTURE	UPPER LIMB FRACTURE	DISTAL RADIUS FRACTURE OF LEFT UPPER LIMB
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	CONTUSION	DOWNFALL WITH CONTUSION AND RESULTING HAEMATOMA OF RIGHT THIGH
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACE INJURY	FACE INJURY	FACE INJURY DUE TO FALL
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SUBDURAL HAEMATOMA	SUBDURAL HEMATOMA (TRAUMATIC)	FALL, SUBDURAL HEMATOMA
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	LACERATION OF HEAD	HEAD LACERATION
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	LACERATION OF FACE	PATIENT FELL_ WOUND IN HER FACE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	PROCEDURAL HEADACHE	POST PROCEDURAL HEADACHE	POSTPUNCTINAL HEADACHE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	JOINT SPRAIN	ANKLE SPRAIN	SPRAIN OF LEFT ANKLE
INVESTIGATIONS	BACTERIAL TEST	BACTERIA URINE	ELEVATED BACTERIA (URINE)

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	CRP INCREASED	ELEVATION OF CRP WITH UNKNOWN ORIGIN
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	GAMMA GT INCREASED	HIGHT GAMMA-GT
INVESTIGATIONS	HEPATIC ENZYME INCREASED	ELEVATED LIVER ENZYMES	INCREASE OF SGOT AND SGPT
INVESTIGATIONS	BLOOD CREATININE INCREASED	CREATININE INCREASED	INCREASED CREATININE
INVESTIGATIONS	WHITE BLOOD CELLS URINE	WHITE BLOOD CELLS URINE	LEUCOZYTEN IN URINE
INVESTIGATIONS	WEIGHT DECREASED	LOSS OF WEIGHT	LOSS OF WEIGHT
INVESTIGATIONS	ELECTROCARDIOGRAM LOW VOLTAGE	ELECTROCARDIOGRAM LOW VOLTAGE	PERIPHERAL LOW VOLTAGE
INVESTIGATIONS	WHITE BLOOD CELLS URINE POSITIVE	URINE WHITE BLOOD CELL INCREASED	RECURRENT ELEVATED LEUCOCYTES IN URIN
INVESTIGATIONS	URINARY SEDIMENT PRESENT	EPITHELIAL CELLS URINE	SLIGHT ELEVATED EPITHELIAL CELLS IN URINE
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	NEUTROPHILS INCREASED	SLIGHT ELEVATED NEUTROPHILE GRANULOCYTES
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	ELECTROCARDIOGRAM QTC INTERVAL PROLONGED	SLIGHT INCREASE OF QTC (445MS)
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	ELECTROCARDIOGRAM QTC INTERVAL PROLONGED	SLIGHT INCREASE OF QTC (453MS)
INVESTIGATIONS	ELECTROCARDIOGRAM POOR R-WAVE PROGRESSION	ELECTROCARDIOGRAM POOR R-WAVE PROGRESSION	SLOW R WAVE PROGRESSION
INVESTIGATIONS	WEIGHT DECREASED	WEIGHT LOSS	WEIGHT LOSS
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	DECREASED APPETITE	FASTER SATED
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	APPETITE LOST	LOSS OF APPETITE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	POTASSIUM DEFICIENCY	POTASSIUM DEFICIENCY

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
METABOLISM AND NUTRITION DISORDERS	VITAMIN B COMPLEX DEFICIENCY	UNSPECIFIED VITAMIN B DEFICIENCY	VITAMIN B12 DEFICIENCY
METABOLISM AND NUTRITION DISORDERS	VITAMIN D DEFICIENCY	VITAMIN D DEFICIENCY	VITAMIN D3 DEFICIENCY
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	BACK PAIN	BACK PAIN
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	CRAMPS CALF	CRAMP IN THE CALF
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	CRAMPS	CRAMPS IN THE HANDS
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	JOINT PAIN	JOINT PAIN
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	LUMBAGO	LUMBAGO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	COCCYDYNIA	COCCYALGIA	PAIN COCCYX
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	CALF PAIN	PAIN IN BOTH CALFS
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	JOINT PAIN	PAIN IN JOINTS
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	SHOULDER PAIN	PAIN IN RIGHT SHOULDER
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	SHOULDER PAIN	PAIN IN SHOULDER
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	GENERALIZED JOINT PAIN	PAIN IN THE JOINTS
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	KNEE PAIN	PAIN IN THE LEFT KNEE

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	PAIN IN HAND	PAIN IN THE THENAR
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BONE PAIN	BONE PAIN	PAIN OF THE BONES
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	COXALGIA	PAIN OF THE HIP
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	GENERALIZED JOINT PAIN	PAIN OF THE JOINTS
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	LOW BACK PAIN	RECURRENT PAIN IN THE LOWER BACK
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	SHOULDER PAIN	SCAPULA PAIN LEFT
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	PAIN NECK/SHOULDER	SHOULDER AND NECK PAIN
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL COLUMN STENOSIS	SPINAL STENOSIS NOS	WORSENING OF CHRONIC BACK PAIN DUE TO SPINAL CANAL STENOSIS
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	BENIGN NEOPLASM OF ADRENAL GLAND	BENIGN ADRENAL NEOPLASM NOS	ADRENAL TUMOR BENIGN
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	LIPOMA	LIPOMA OF OTHER SPECIFIED SITES	LIPOMA BACK LEFT
NERVOUS SYSTEM DISORDERS	COGNITIVE DISORDER	COGNITIVE DETERIORATION	COGNITION WORSENING
NERVOUS SYSTEM DISORDERS	COGNITIVE DISORDER	COGNITIVE IMPAIRMENT	COGNITIVE DECLINE
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	HYPOAESTHESIA	DEAFNESS OF LEFT FACE, ARM AND FOOT
NERVOUS SYSTEM DISORDERS	DIZZINESS	DIZZINESS	DIZZINESS
NERVOUS SYSTEM DISORDERS	DIZZINESS	DIZZINESS	DIZZINESS AND NAUSEA

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
NERVOUS SYSTEM DISORDERS	DIZZINESS	DIZZINESS	DIZZINESS AND NAUSEA, BLURRED VISION
NERVOUS SYSTEM DISORDERS	EPILEPSY	EPILEPTIFORM ATTACKS (NOS)	EPILEPTIC TYPICAL SPIKES AND SERIES OF SPIKES ON EEG, DURING THE NEUROPSYCHOLOGICAL EXAMINATION PROBABLE ABSENCE FOR FEW SECONDS.
NERVOUS SYSTEM DISORDERS	ESSENTIAL TREMOR	ESSENTIAL TREMOR	ESSENTIAL TREMOR
NERVOUS SYSTEM DISORDERS	HEADACHE	HEADACHE	HEADACHE
NERVOUS SYSTEM DISORDERS	HEADACHE	HEADACHE	HEADACHE (AFTER LP)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	HYPOESTHESIA	HYPOSTHESIA RIGHT ARM
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	PARESTHESIA UPPER LIMB	LEFT ARM PRICKLING
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	NUMBNESS	NUMBNESS
NERVOUS SYSTEM DISORDERS	FACIAL PALSY	PARALYSIS FACIAL	PARALYSIS OF THE LEFT SIDE OF HER FACE.
NERVOUS SYSTEM DISORDERS	PARKINSONISM	PARKINSON'S SYNDROME	PARKINSON SYNDROME
NERVOUS SYSTEM DISORDERS	DIZZINESS	DIZZINESS	PATIENT FEELING DIZZY.
NERVOUS SYSTEM DISORDERS	DEMENTIA ALZHEIMER'S TYPE	PROGRESSION OF ALZHEIMER'S DISEASE	PROGRESSION OF ALZHEIMERS DISEASE
NERVOUS SYSTEM DISORDERS	SCIATICA	LUMBOISCHIALGIA	RENEWED RIGHT LUMBOISCHIALGIA
NERVOUS SYSTEM DISORDERS	HEADACHE	HEADACHE	SLIGHT HEADACHE
NERVOUS SYSTEM DISORDERS	SYNCOPE	SYNCOPE	SYNCOPE
NERVOUS SYSTEM DISORDERS	TREMOR	TREMOR LIMB	UPPER LIMB SHAKING
NERVOUS SYSTEM DISORDERS	SYNCOPE	SYNCOPE VASOVAGAL	VASOVAGAL SYNCOPE
NERVOUS SYSTEM DISORDERS	ATAXIA	ATAXIA AGGRAVATED	WORSENING OF ATAXIA RIGHT ARM
NERVOUS SYSTEM DISORDERS	DEMENTIA	DEMENTIA AGGRAVATED	WORSENING OF DEMENTIA
PSYCHIATRIC DISORDERS	AGGRESSION	AGGRESSION	AGGRESSION
PSYCHIATRIC DISORDERS	AGGRESSION	AGGRESSIVE BEHAVIOUR	AGGRESSIVE BEHAVIOR
PSYCHIATRIC DISORDERS	AGGRESSION	AGGRESSIVE BEHAVIOUR	AGGRESSIVE BEHAVIOUR

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
PSYCHIATRIC DISORDERS	AGITATION	AGITATION	AGITATION
PSYCHIATRIC DISORDERS	AGGRESSION	AGGRESSION	AGRESSION
PSYCHIATRIC DISORDERS	ANXIETY	ANXIETY	ANXIETY
PSYCHIATRIC DISORDERS	APATHY	APATHY	APATHY
PSYCHIATRIC DISORDERS	ABNORMAL DREAMS	BAD DREAMS	BAD DREAMS
PSYCHIATRIC DISORDERS	DEPRESSION	DEPRESSION	DEPRESSION DUE TO AD
PSYCHIATRIC DISORDERS	DISORIENTATION	DISORIENTATION	DISORIENTATION
PSYCHIATRIC DISORDERS	DISORIENTATION	AGGRAVATION OF EXISTING DISORDER	FURTHER WORSENING OF ORIENTATION
PSYCHIATRIC DISORDERS	ABNORMAL BEHAVIOUR	BEHAVIOR DISORDER	INCREASING PSYCHOPATHOLOGICAL SYMPTOMS
PSYCHIATRIC DISORDERS	INSOMNIA	INSOMNIA	INSOMNIA
PSYCHIATRIC DISORDERS	DELUSIONAL DISORDER, UNSPECIFIED TYPE	DELUSIONAL DISORDER, UNSPECIFIED TYPE	INTERMITTENT DELUSIONAL SYMPTOMS
PSYCHIATRIC DISORDERS	DISORIENTATION	DISORIENTATION	LOCAL DESORIENTATION
PSYCHIATRIC DISORDERS	MAJOR DEPRESSION	MELANCHOLIA	MELANCHOLIC FEELING
PSYCHIATRIC DISORDERS	AGITATION	NOCTURNAL AGITATION	NOCTURNAL RESTLESSNESS AND EXCITATION
PSYCHIATRIC DISORDERS	NERVOUSNESS	NERVOUSNESS	PATIENT IS FEELING NERVOUS.
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	PSYCHOSIS	PSYCHOSIS (DELUSIONS AND HALLUZINATIONS)
PSYCHIATRIC DISORDERS	ALCOHOLISM	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE	RELAPSE OF ALCOHOL DEPENDENCE
PSYCHIATRIC DISORDERS	RESTLESSNESS	RESTLESSNESS	RESTLESSNESS DURING NIGHT
PSYCHIATRIC DISORDERS	RESTLESSNESS	UNREST	UNREST
PSYCHIATRIC DISORDERS	HALLUCINATION	HALLUCINATIONS	VISIONS
PSYCHIATRIC DISORDERS	AGGRESSION	AGGRESSION AGGRAVATED	WORSENING OF AGGRESSION
PSYCHIATRIC DISORDERS	AGGRESSION	AGGRESSION AGGRAVATED	WORSENING OF AGRESSION
PSYCHIATRIC DISORDERS	DEPRESSION	DEPRESSION AGGRAVATED	WORSENING OF DEPRESSION

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS	DISORIENTATION PSYCHOTIC DISORDER	DISORIENTATION PSYCHOSIS AGGRAVATED	WORSENING OF ORIENTATION WORSENING PYCHOSIS (DELUSIONS AND HALLUZINATIONS)
RENAL AND URINARY DISORDERS RENAL AND URINARY DISORDERS RENAL AND URINARY DISORDERS RENAL AND URINARY DISORDERS RENAL AND URINARY DISORDERS RENAL AND URINARY DISORDERS	PROTEINURIA POLLAKIURIA INCONTINENCE INCONTINENCE HAEMATURIA BLADDER PAIN	PROTEINURIA MICTRUTION FREQUENT INCONTINENCE INCONTINENCE MICROSCOPIC HEMATURIA PAIN BLADDER	ELEVATED PROTEIN (URINE) FREQUENT MICTURITION INCONTINENCE INCONTINENZ INDIFFERENT MICROHAEMATURIA PAIN OF THE BLADDER
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONIA ASPIRATION PULMONARY MASS COUGH DYSPNOEA	ASPIRATION PNEUMONIA LUNG MASS COUGH DYSPNEA	ASPIRATION PNEUMONIA COIN SHAPED DENSITY UNSPECIFIC IN THE LUNG COUGH DYSPNEA
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS MEDIASTINAL DISORDERS SKIN AND SUBCUTANEOUS TISSUE DISORDERS SKIN AND SUBCUTANEOUS TISSUE DISORDERS SKIN AND SUBCUTANEOUS TISSUE DISORDERS SKIN AND SUBCUTANEOUS TISSUE DISORDERS	EMPHYSEMA DERMATITIS ATOPIC ACNE INTERTRIGO RASH	EMPHYSEMA PULMONARY ATOPIC DERMATITIS COMEDO GROIN INTERTRIGO RASH	PULMONARY EMPHYSEMA ATOPIC DERMATITIS COMEDO IN FACE INGUINAL INTERTRIGO BOTH SIDES RUSH LEFT LEG
SURGICAL AND MEDICAL PROCEDURES	CATARACT OPERATION	LEFT CATARACT EXTRACTION	CATARACT SURGERY LEFT EYE

Listing 16.2.7.2: MedDRA (Version 12.1) adverse events and associated Investigators Term

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System organ class	Preferred term	Lower level term	Investigators Term
SURGICAL AND MEDICAL PROCEDURES	CATARACT OPERATION	CATARACT OPERATION	PLANNED SURGERY OF CATARACTA
SURGICAL AND MEDICAL PROCEDURES	ENDODONTIC PROCEDURE	ROOT CANAL PROCEDURE	CORTICONUCLEARIS SENILIS ROOT RESECTION
SURGICAL AND MEDICAL PROCEDURES	EYE OPERATION	EYE OPERATION	SURGERY TO REMOVE CICATRICE AFTER KATARACT EXCISION
VASCULAR DISORDERS	HYPERTENSION	HYPERTENSION ARTERIAL	ARTERIAL HYPERTENSION
VASCULAR DISORDERS	CIRCULATORY COLLAPSE	COLLAPSE	COLLAPSE AND DOWNFALL
VASCULAR DISORDERS	HAEMATOMA	HEMATOMA	HEMATOMA ON NOSE
VASCULAR DISORDERS	HAEMATOMA	HEMATOMA	HEMATOMA RIGHT THIGH
VASCULAR DISORDERS	HYPERTENSION	BLOOD PRESSURE HIGH	HIGH BLOOD PRESSURE
VASCULAR DISORDERS	HOT FLUSH	HOT FLUSHES	HOT FLASHES
VASCULAR DISORDERS	HYPERTENSION	HYPERTENSION	HYPERTENSION
VASCULAR DISORDERS	HYPOTENSION	HYPOTENSIVE EPISODE	HYPOTENSIVE EPISODE
VASCULAR DISORDERS	PELVIC VENOUS THROMBOSIS	THROMBOPHLEBITIS PELVIC VEIN	PELVIC VEIN THROMBOSIS
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	DEEP VEIN THROMBOSIS LEG	THROMBOSIS IN THE LEFT VENA FIBULARIS
VASCULAR DISORDERS	HYPERTENSION	HYPERTENSION AGGRAVATED	WORSENING HYPERTENSION

Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	002	1	SCREENING	-7	16APR2009	10:00	YES	NO	
			V1 (WEEK 0)	1	23APR2009	8:55	YES	NO	
			V3 (WEEK 12)	85	16JUL2009	8:30	YES	NO	
			V4 (WEEK 24)	169	08OCT2009	10:30	YES	NO	
			V5 (WEEK 36)	258	05JAN2010	9:25	YES	NO	
			V6 (WEEK 52)	365	22APR2010	10:10	YES	NO	
			V7 (WEEK 56)	393	20MAY2010	9:15	YES	NO	
	004	1	SCREENING	-29	17JUN2009	11:40	YES	NO	
			V1 (WEEK 0)	1	16JUL2009	10:00	YES	NO	
			V3 (WEEK 12)	92	15OCT2009	14:50	YES	NO	
	006	2	SCREENING	-32	25JAN2010	8:45	YES	NO	
			V1 (WEEK 0)	1	26FEB2010	9:00	YES	NO	
			V3 (WEEK 12)	85	21MAY2010	9:15	YES	NO	
			V4 (WEEK 24)	169	13AUG2010	9:00	YES	NO	
			V5 (WEEK 36)	252	04NOV2010	8:30	YES	NO	
			V6 (WEEK 52)	364	24FEB2011	8:20	YES	NO	
			V7 (WEEK 56)	390	22MAR2011	8:30	YES	NO	
	010	1	SCREENING	-26	25JUN2009	9:45	YES	NO	
			V1 (WEEK 0)	1	21JUL2009	11:00	YES	NO	
			V3 (WEEK 12)	85	13OCT2009	10:45	YES	NO	

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	012	1	SCREENING	-32	17JUN2010	12:20	YES	NO	
			V1 (WEEK 0)	1	19JUL2010	10:00	YES	NO	
			V3 (WEEK 12)	88	14OCT2010	9:15	YES	YES	INCREASE OF SGOT AND SGPT
			V4 (WEEK 24)	176	10JAN2011	10:50			
			V5 (WEEK 36)	257	01APR2011	9:30	YES	NO	
			V6 (WEEK 52)	361	14JUL2011	10:25	YES	NO	
			V7 (WEEK 56)	396	18AUG2011	12:20	YES	NO	
	014	4	SCREENING	-26	07OCT2009	11:30	YES	NO	
			V1 (WEEK 0)	1	02NOV2009	9:30	YES	NO	
			V3 (WEEK 12)	85	25JAN2010	10:00	YES	NO	
			V4 (WEEK 24)	172	22APR2010	10:15	YES	NO	
			V5 (WEEK 36)	256	15JUL2010	10:30	YES	NO	
			V6 (WEEK 52)	361	28OCT2010	11:00	YES	NO	
			V7 (WEEK 56)	396	02DEC2010	11:30	YES	NO	
	015	4	SCREENING	-32	21JAN2010	10:30	YES	NO	
			V1 (WEEK 0)	1	22FEB2010	9:00	YES	NO	
			V3 (WEEK 12)	85	17MAY2010	10:00	YES	NO	
			V4 (WEEK 24)	162	02AUG2010	9:30	YES	NO	
			V5 (WEEK 36)	248	27OCT2010	9:45	YES	NO	
			V6 (WEEK 52)	365	21FEB2011	10:30	YES	NO	
			V7 (WEEK 56)	394	22MAR2011	10:15	YES	NO	

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	017	5	SCREENING	-22	14JUL2009	10:30	YES	NO	
			V1 (WEEK 0)	1	05AUG2009	9:00	YES	NO	
			V3 (WEEK 12)	85	28OCT2009	8:45	YES	NO	
			V4 (WEEK 24)	169	20JAN2010	9:00	YES	NO	
			V5 (WEEK 36)	252	13APR2010	10:45	YES	NO	
			V6 (WEEK 52)	364	03AUG2010	9:00	YES	NO	
			V7 (WEEK 56)	392	31AUG2010	9:00	YES	NO	
	019	5	SCREENING	-21	18NOV2009	13:00	YES	NO	
			V1 (WEEK 0)	1	09DEC2009	9:00	YES	NO	
			V3 (WEEK 12)	85	03MAR2010	9:00	YES	NO	
			V4 (WEEK 24)	168	25MAY2010	9:00	YES	NO	
			V5 (WEEK 36)	259	24AUG2010	12:00	YES	NO	
			V6 (WEEK 52)	364	07DEC2010	13:30	YES	NO	
			V7 (WEEK 56)	399	11JAN2011	9:10	YES	NO	
	023	4	SCREENING	-19	01JUL2010	11:00	YES	NO	
			V1 (WEEK 0)	1	20JUL2010	10:00	YES	NO	
			V3 (WEEK 12)	86	13OCT2010	9:30	YES	NO	
			V4 (WEEK 24)	177	12JAN2011	10:30	YES	NO	
			V5 (WEEK 36)	245	21MAR2011	9:45	YES	NO	
			V6 (WEEK 52)	364	18JUL2011	10:00	YES	NO	
			V7 (WEEK 56)	388	11AUG2011	11:15			

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	027	20	SCREENING	-21	30SEP2010	10:35	YES	YES	LEUCOYTES ELEVATED
			V1 (WEEK 0)	1	21OCT2010	9:15	YES	YES	LEUCOCYTES ELEVATED
			V3 (WEEK 12)	92	20JAN2011	10:55	YES	NO	
			V4 (WEEK 24)	174	12APR2011	10:30	YES	NO	
			V5 (WEEK 36)	259	06JUL2011	10:55	YES	NO	
			V6 (WEEK 52)	370	25OCT2011	8:19	YES	NO	
			V7 (WEEK 56)	407	01DEC2011	10:10	YES	NO	
	030	8	SCREENING	-7	18MAR2010	10:30	YES	NO	
			V1 (WEEK 0)	1	25MAR2010	10:20	YES	NO	
			V3 (WEEK 12)	85	17JUN2010	11:50	YES	NO	
			V4 (WEEK 24)	163	03SEP2010	12:30	YES	NO	
			V5 (WEEK 36)	253	02DEC2010	12:50	YES	NO	
			V6 (WEEK 52)	355	14MAR2011	11:00	YES	NO	
			V7 (WEEK 56)	383	11APR2011	11:30	YES	NO	
	032	8	SCREENING	-10	08NOV2010	10:00	YES	YES	EOS. GRANULOCYTES 0.4 % CHOLESTEROL 6.66 MMOL/L
			V1 (WEEK 0)	1	18NOV2010	10:10	YES	YES	EOSINOPHILE GRANULOCYTES 0,6%
			V3 (WEEK 12)	82	07FEB2011	12:23	YES	YES	EOSINOPHILE GRANULOCYTES 0,7 % CHOLESTEROL 7,46 MMOL/L
	033	9	SCREENING	-7	28OCT2009	8:15	YES	NO	
			V1 (WEEK 0)	1	04NOV2009	8:00	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	033	9	V3 (WEEK 12)	78	20JAN2010	9:05	YES	NO	
			V4 (WEEK 24)	169	21APR2010	9:30	YES	NO	
			V5 (WEEK 36)	261	22JUL2010	8:30	YES	NO	
			V6 (WEEK 52)	372	10NOV2010	8:30	YES	NO	
			V7 (WEEK 56)	398	06DEC2010	8:45	YES	NO	
	042	12	SCREENING	-29	16DEC2009	9:30	YES	NO	
			V1 (WEEK 0)	1	14JAN2010	9:15	YES	NO	
			V3 (WEEK 12)	126	19MAY2010	8:30	YES	NO	
			V4 (WEEK 24)	168	30JUN2010	8:45	YES	NO	
			V5 (WEEK 36)	252	22SEP2010	8:30	YES	NO	
			V6 (WEEK 52)	364	12JAN2011	8:30	YES	NO	
			V7 (WEEK 56)	391	08FEB2011	8:40	YES	NO	
	043	12	SCREENING	-28	21OCT2009	9:45	YES	NO	
			V1 (WEEK 0)	1	18NOV2009	9:30	YES	NO	
			V3 (WEEK 12)	85	10FEB2010	9:30	YES	NO	
			V4 (WEEK 24)	176	12MAY2010	9:00	YES	NO	
	046	11	SCREENING	-28	14DEC2009	9:30	YES	YES	ELEVATED CREATININE, UREA, CHOLESTEROL
			UNSCHEDULED	-21	21DEC2009	13:10	YES	YES	CREATININE VALUE AT UNSCHEDULED VISIT WAS 1,4 MG/DL.
			V1 (WEEK 0)	1	11JAN2010	9:45	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	046	11	V3 (WEEK 12)	87	07APR2010	9:30	YES	NO	
			V4 (WEEK 24)	178	07JUL2010	9:30	YES	NO	
			V5 (WEEK 36)	255	22SEP2010	11:40	YES	YES	ELEVATED CREATININE
			V6 (WEEK 52)	367	12JAN2011	8:00	YES	YES	CREATININE ELEVATED TO 118,5 MICROMOL/L
			V7 (WEEK 56)	393	07FEB2011	8:15	YES	YES	CREATININE ELEVATED TO 156,5 MICROMOL/L, PROTEIN+BACTERIA IN URINE
	048	11	SCREENING	-5	17NOV2010	11:10	YES	NO	
			V1 (WEEK 0)	1	22NOV2010	10:30	YES	NO	
			V3 (WEEK 12)	86	15FEB2011	11:00	YES	NO	
			V4 (WEEK 24)	176	16MAY2011	10:30	YES	NO	
			V5 (WEEK 36)	247	26JUL2011	10:40	YES	NO	
			V6 (WEEK 52)	360	16NOV2011	10:00	YES	NO	
			V7 (WEEK 56)	395	21DEC2011	11:20	YES	NO	
	050	21	SCREENING	-51	06SEP2010	14:30	YES	NO	
			V1 (WEEK 0)	1	27OCT2010	11:45	YES	NO	
			V3 (WEEK 12)	83	17JAN2011	11:15	YES	NO	
			V4 (WEEK 24)	167	11APR2011	11:20	YES	NO	
			UNSCHEDULED	211	25MAY2011	9:30	YES	NO	
			V5 (WEEK 36)	251	04JUL2011	11:50	YES	NO	
			V6 (WEEK 52)	363	24OCT2011	9:00	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	050	21	UNSCHEDULED	366	27OCT2011	11:42	YES	NO	
			V7 (WEEK 56)	391	21NOV2011	8:51	YES	NO	
	052	21	SCREENING	-52	06SEP2010	14:15	YES	YES	B12 102 PMOL
			V1 (WEEK 0)	1	28OCT2010	8:15	YES	NO	
			V3 (WEEK 12)	82	17JAN2011	10:45	YES	NO	
			V4 (WEEK 24)	166	11APR2011	10:45	YES	NO	
			V5 (WEEK 36)	250	04JUL2011	9:24	YES	NO	
			V6 (WEEK 52)	362	24OCT2011	12:15	YES	NO	
			V7 (WEEK 56)	390	21NOV2011	9:46	YES	NO	
	055	5	SCREENING	-21	08MAR2010	11:30	YES	NO	
			V1 (WEEK 0)	1	29MAR2010	9:30	YES	NO	
			V6 (WEEK 52)	30	27APR2010	9:15	YES	NO	
	057	1	SCREENING	-21	29JUL2010	10:50	YES	NO	
			V1 (WEEK 0)	1	19AUG2010	11:10	YES	NO	
			V3 (WEEK 12)	82	08NOV2010	9:45	YES	NO	
			V4 (WEEK 24)	170	04FEB2011	9:35	YES	NO	
	066	16	SCREENING	-31	09AUG2010	10:40	YES	NO	
			UNSCHEDULED	-3	06SEP2010	9:00	YES	NO	
			V1 (WEEK 0)	1	09SEP2010	9:25	YES	NO	
			V3 (WEEK 12)	83	30NOV2010	9:15	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	067	16	SCREENING	-16	02NOV2010	10:40	YES	NO	
			UNSCHEDULED	-7	11NOV2010	10:00	YES	NO	
			V1 (WEEK 0)	1	18NOV2010	8:30	YES	NO	
			V6 (WEEK 52)	69	25JAN2011	10:50	YES	NO	
			V7 (WEEK 56)	111	08MAR2011	9:05	YES	NO	
	071	18	SCREENING	-20	20OCT2010	10:05	YES	NO	
			V1 (WEEK 0)	1	09NOV2010	11:00	YES	NO	
			V3 (WEEK 12)	87	03FEB2011	10:07	YES	YES	GAMMA-GT
			UNSCHEDULED	99	15FEB2011	10:20	YES	YES	GAMMA-GT 148 U/L
			UNSCHEDULED	155	12APR2011	10:10	YES	NO	
			V4 (WEEK 24)	177	04MAY2011	9:35	YES	NO	
			V5 (WEEK 36)	253	19JUL2011	9:41	YES	NO	
			V6 (WEEK 52)	374	17NOV2011	11:02	YES	NO	
			V7 (WEEK 56)	392	05DEC2011	12:01	YES	NO	
	080	13	SCREENING	-10	08NOV2010	10:27	YES	NO	
			V1 (WEEK 0)	1	18NOV2010	12:30	YES	NO	
			UNSCHEDULED	42	29DEC2010	14:40	YES	YES	CREATININ 135.3 MICROMOL/L
			V3 (WEEK 12)	84	09FEB2011	11:30	YES	NO	
			V6 (WEEK 52)	196	01JUN2011	12:30	YES	NO	
	081	17	SCREENING	-10	04OCT2010	11:20	YES	NO	
			V1 (WEEK 0)	1	14OCT2010	10:00	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	11:15	YES	NO	
			V4 (WEEK 24)	175	06APR2011	9:30	YES	NO	
			V5 (WEEK 36)	250	20JUN2011	11:00	YES	NO	
			V6 (WEEK 52)	376	24OCT2011	10:35	YES	NO	
			V7 (WEEK 56)	405	22NOV2011	10:45	YES	NO	
	083	17	SCREENING	-15	26OCT2010	11:30	YES	NO	
			V1 (WEEK 0)	1	10NOV2010	9:25	YES	NO	
			V4 (WEEK 24)	168	26APR2011	10:15	YES	NO	
			V5 (WEEK 36)	258	25JUL2011	10:50	YES	NO	
			V6 (WEEK 52)	365	09NOV2011	10:20	YES	NO	
			V7 (WEEK 56)	392	06DEC2011	10:20	YES	NO	
	087	16	SCREENING	-20	09NOV2010	9:05	YES	NO	
			V1 (WEEK 0)	1	29NOV2010	10:10	YES	NO	
			V3 (WEEK 12)	81	17FEB2011	9:35	YES	NO	
			V4 (WEEK 24)	169	16MAY2011	11:00	YES	NO	
			V5 (WEEK 36)	255	10AUG2011	10:20	YES	NO	
			V6 (WEEK 52)	365	28NOV2011	10:15	YES	NO	
			V7 (WEEK 56)	395	28DEC2011	12:00	YES	NO	
	089	5	SCREENING	-28	19OCT2010	12:00	YES	NO	
			V1 (WEEK 0)	1	16NOV2010	12:00	YES	NO	
			V3 (WEEK 12)	84	07FEB2011	11:30	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	089	5	V4 (WEEK 24)	168	02MAY2011	10:15	YES	NO	
			V5 (WEEK 36)	252	25JUL2011	12:00	YES	NO	
			V6 (WEEK 52)	364	14NOV2011	12:30	YES	NO	
			V7 (WEEK 56)	394	14DEC2011	13:00	YES	NO	
	093	17	SCREENING	-3	29NOV2010	12:30	YES	NO	
			V1 (WEEK 0)	1	02DEC2010	8:30	YES	NO	
			V3 (WEEK 12)	86	25FEB2011	11:35	YES	NO	
			V4 (WEEK 24)	173	23MAY2011	11:45	YES	NO	
			V5 (WEEK 36)	258	16AUG2011	10:30	YES	NO	
			V6 (WEEK 52)	370	06DEC2011	10:40	YES	NO	
			V7 (WEEK 56)	392	28DEC2011	10:15	YES	NO	
	097	12	SCREENING	-21	27OCT2010	8:30	YES	NO	
			V1 (WEEK 0)	1	17NOV2010	8:30	YES	NO	
			V3 (WEEK 12)	85	09FEB2011	8:15	YES	NO	
Placebo	001	1	SCREENING	-7	02APR2009	10:40	YES	NO	
			V1 (WEEK 0)	1	09APR2009	10:30	YES	NO	
			V3 (WEEK 12)	90	07JUL2009	8:55	YES	NO	
			V4 (WEEK 24)	162	17SEP2009	11:00	YES	NO	
			V5 (WEEK 36)	246	10DEC2009	9:10	YES	NO	
			V6 (WEEK 52)	365	08APR2010	9:00	YES	NO	
			V7 (WEEK 56)	393	06MAY2010	13:15	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	003	1	SCREENING	-21	07MAY2009	10:10	YES	NO	
			V1 (WEEK 0)	1	28MAY2009	11:25	YES	NO	
			V3 (WEEK 12)	90	25AUG2009	11:50	YES	NO	
			V4 (WEEK 24)	169	12NOV2009	10:15	YES	NO	
	005	2	SCREENING	-16	19MAY2009	14:00	YES	NO	
			V1 (WEEK 0)	1	04JUN2009	8:45	YES	NO	
			V3 (WEEK 12)	83	25AUG2009	8:30	YES	NO	
			V4 (WEEK 24)	168	18NOV2009	10:00	YES	NO	
			V5 (WEEK 36)	258	16FEB2010	9:00	YES	NO	
			V6 (WEEK 52)	364	02JUN2010	9:00	YES	NO	
			V7 (WEEK 56)	400	08JUL2010	9:15	YES	NO	
	009	1	SCREENING	-33	06AUG2009	11:45	YES	NO	
			V1 (WEEK 0)	1	08SEP2009	9:10	YES	NO	
			V3 (WEEK 12)	94	10DEC2009	9:40	YES	NO	
			V4 (WEEK 24)	178	04MAR2010	12:50	YES	NO	
			V5 (WEEK 36)	246	11MAY2010	10:20	YES	NO	
			V6 (WEEK 52)	361	03SEP2010	10:15	YES	NO	
			V7 (WEEK 56)	389	01OCT2010	9:15	YES	NO	
	011	1	SCREENING	-21	05NOV2009	13:10	YES	NO	
			V1 (WEEK 0)	1	26NOV2009	10:25	YES	NO	
			V3 (WEEK 12)	85	18FEB2010	9:05	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	011	1	V4 (WEEK 24)	162	06MAY2010	13:30	YES	NO	
			V5 (WEEK 36)	253	05AUG2010	12:10	YES	NO	
			V6 (WEEK 52)	366	26NOV2010	10:10	YES	NO	
			V7 (WEEK 56)	397	27DEC2010	12:30	YES	NO	
	013	4	SCREENING	-30	17AUG2009	10:00	YES	NO	
			V1 (WEEK 0)	1	16SEP2009	9:00	YES	NO	
			V3 (WEEK 12)	85	09DEC2009	10:00	YES	NO	
			V4 (WEEK 24)	170	04MAR2010	10:00	YES	NO	
			V5 (WEEK 36)	247	20MAY2010	10:25	YES	NO	
			V6 (WEEK 52)	366	16SEP2010	11:00	YES	NO	
			V7 (WEEK 56)	400	20OCT2010	11:45	YES	NO	
	016	4	SCREENING	-28	01FEB2010	10:00	YES	YES	HYPERCHOLESTERINEMIA
			V1 (WEEK 0)	1	01MAR2010	10:00	YES	YES	HYPERCHOLESTERINEMIA
			V3 (WEEK 12)	80	19MAY2010	9:15	YES	NO	
			V4 (WEEK 24)	162	09AUG2010	10:20	YES	NO	
			V5 (WEEK 36)	253	08NOV2010	9:45	YES	NO	
			V6 (WEEK 52)	365	28FEB2011	10:30	YES	NO	
			V7 (WEEK 56)	403	07APR2011	11:00	YES	NO	
	018	5	SCREENING	-20	03NOV2009	13:15	YES	NO	
			V1 (WEEK 0)	1	23NOV2009	13:00	YES	NO	
			V3 (WEEK 12)	86	16FEB2010	12:45	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	018	5	V4 (WEEK 24)	170	11MAY2010	9:00	YES	NO	
			V5 (WEEK 36)	247	27JUL2010	9:00	YES	NO	
			V6 (WEEK 52)	366	23NOV2010	9:20	YES	NO	
			V7 (WEEK 56)	387	14DEC2010	8:50	YES	NO	
	020	5	SCREENING	-26	27JAN2010	15:30	YES	NO	
			V1 (WEEK 0)	1	22FEB2010	13:20	YES	NO	
	024	4	SCREENING	-31	16JUL2010	9:30	YES	NO	
			V1 (WEEK 0)	1	16AUG2010	9:30	YES	NO	
			V3 (WEEK 12)	87	10NOV2010	10:20	YES	NO	
			V4 (WEEK 24)	171	02FEB2011	9:30	YES	NO	
			V5 (WEEK 36)	246	18APR2011	10:00	YES	NO	
			V6 (WEEK 52)	358	08AUG2011	9:30	YES	NO	
			V7 (WEEK 56)	393	12SEP2011	11:40	YES	NO	
	028	20	SCREENING	-8	18NOV2010	10:20	YES	NO	
			V1 (WEEK 0)	1	26NOV2010	9:15	YES	NO	
			V3 (WEEK 12)	89	22FEB2011	10:20	YES	YES	MONOCYTOSIS, PATIENT WAS IN THE INTERNAL WARD
			V4 (WEEK 24)	180	24MAY2011	10:05	YES	NO	
			V5 (WEEK 36)	273	25AUG2011	10:45	YES	NO	
			V6 (WEEK 52)	364	24NOV2011	8:09	YES	NO	
			V7 (WEEK 56)	390	20DEC2011	10:15	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	029	8	SCREENING	-3	26JAN2010	9:45	YES	NO	
			V1 (WEEK 0)	1	29JAN2010	10:00	YES	NO	
			V3 (WEEK 12)	82	20APR2010	11:50	YES	NO	
			V4 (WEEK 24)	158	05JUL2010	11:10	YES	NO	
			V5 (WEEK 36)	245	30SEP2010	11:25	YES	YES	U. LEUCOCYTES 25/UL_ Erys 3-6/HPF_ LEUCOS >50/HPF_ ROUND EPIT. 3-5/HPF
			V6 (WEEK 52)	369	01FEB2011	11:45	YES	NO	
			V7 (WEEK 56)	391	23FEB2011	11:05	YES	YES	NEUTROPHILE GRANULOCYTES 75,0% LYMPHOCYTES 16,1%
	031	8	SCREENING	-14	06MAY2010	13:15	YES	NO	
			V1 (WEEK 0)	1	20MAY2010	10:00	YES	NO	
			V3 (WEEK 12)	90	17AUG2010	10:45	YES	NO	
			V4 (WEEK 24)	174	09NOV2010	11:35	YES	NO	
			V5 (WEEK 36)	251	25JAN2011	12:00	YES	NO	
			V6 (WEEK 52)	363	17MAY2011	11:40	YES	NO	
			V7 (WEEK 56)	391	14JUN2011	10:14	YES	NO	
	034	9	SCREENING	-22	24FEB2010	8:50	YES	NO	
			V1 (WEEK 0)	1	18MAR2010	8:50	YES	NO	
			V3 (WEEK 12)	83	08JUN2010	9:10	YES	NO	
			V4 (WEEK 24)	175	08SEP2010	8:40	YES	NO	
			V5 (WEEK 36)	258	30NOV2010	8:00	YES	NO	
			V6 (WEEK 52)	363	15MAR2011	8:25	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	034	9	V7 (WEEK 56)	399	20APR2011	8:25	YES	NO	
	041	12	SCREENING	-16	23SEP2009	10:30	YES	NO	
			V1 (WEEK 0)	1	09OCT2009	13:15	YES	NO	
			V3 (WEEK 12)	89	05JAN2010	9:40	YES	NO	
			V4 (WEEK 24)	167	24MAR2010	9:10	YES	NO	
			V5 (WEEK 36)	251	16JUN2010	9:15	YES	NO	
			V6 (WEEK 52)	363	06OCT2010	8:30	YES	NO	
			V7 (WEEK 56)	392	04NOV2010	8:30	YES	NO	
	044	12	SCREENING	-28	04NOV2009	9:25	YES	NO	
			V1 (WEEK 0)	1	02DEC2009	9:40	YES	NO	
			V3 (WEEK 12)	85	24FEB2010	9:20	YES	NO	
			V4 (WEEK 24)	176	26MAY2010	8:30	YES	NO	
			V5 (WEEK 36)	260	18AUG2010	8:30	YES	NO	
			V6 (WEEK 52)	365	01DEC2010	8:15	YES	NO	
			V7 (WEEK 56)	400	05JAN2011	9:10	YES	NO	
	045	11	SCREENING	-14	07DEC2009	9:45	YES	NO	
			V1 (WEEK 0)	1	21DEC2009	9:15	YES	NO	
			V3 (WEEK 12)	85	15MAR2010	8:30	YES	NO	
			V4 (WEEK 24)	169	07JUN2010	9:45	YES	NO	
			V5 (WEEK 36)	260	06SEP2010	9:15	YES	NO	
			V6 (WEEK 52)	360	15DEC2010	8:30	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	045	11	V7 (WEEK 56)	393	17JAN2011	9:05	YES	NO	
	047	11	SCREENING	-21	12JUL2010	7:55	YES	NO	
			V1 (WEEK 0)	1	02AUG2010	8:45	YES	NO	
			V3 (WEEK 12)	80	20OCT2010	11:40	YES	NO	
			V4 (WEEK 24)	162	10JAN2011	9:30	YES	NO	
			V5 (WEEK 36)	254	12APR2011	9:15	YES	NO	
			V6 (WEEK 52)	360	27JUL2011	7:35	YES	NO	
			V7 (WEEK 56)	393	29AUG2011	7:45	YES	NO	
	049	21	SCREENING	-51	06SEP2010	10:45	YES	NO	
			V1 (WEEK 0)	1	27OCT2010	8:55	YES	NO	
			V3 (WEEK 12)	84	18JAN2011	10:30	YES	NO	
			V4 (WEEK 24)	168	12APR2011	11:00	YES	NO	
			UNSCHEDULED	213	27MAY2011	9:48	YES	NO	
			V5 (WEEK 36)	252	05JUL2011	10:00	YES	NO	
			UNSCHEDULED	258	11JUL2011	9:37	YES	NO	
			UNSCHEDULED	286	08AUG2011	12:20	YES	NO	
	051	21	SCREENING	-52	06SEP2010	12:40	YES	NO	
			V1 (WEEK 0)	1	28OCT2010	11:30	YES	NO	
			V3 (WEEK 12)	97	01FEB2011	11:30	YES	NO	
			V4 (WEEK 24)	167	12APR2011	13:30	YES	NO	
			V5 (WEEK 36)	251	05JUL2011	13:42	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	051	21	V6 (WEEK 52)	363	25OCT2011	8:30	YES	NO	
			V7 (WEEK 56)	391	22NOV2011	8:30	YES	NO	
	056	5	SCREENING	-21	31MAR2010	10:00	YES	NO	
			V1 (WEEK 0)	1	21APR2010	9:15	YES	NO	
			V3 (WEEK 12)	84	13JUL2010	11:15	YES	NO	
			V4 (WEEK 24)	168	05OCT2010	9:15	YES	NO	
			V5 (WEEK 36)	259	04JAN2011	8:50	YES	NO	
			V6 (WEEK 52)	364	19APR2011	8:05	YES	NO	
			V7 (WEEK 56)	393	18MAY2011	11:20	YES	NO	
	058	1	SCREENING	-21	06DEC2010	10:00	YES	NO	
			V1 (WEEK 0)	1	27DEC2010	11:15	YES	NO	
			V3 (WEEK 12)	93	29MAR2011	11:10	YES	NO	
			V4 (WEEK 24)	166	10JUN2011	10:15	YES	NO	
			V5 (WEEK 36)	260	12SEP2011	10:55	YES	NO	
			V6 (WEEK 52)	345	06DEC2011	9:15	YES	NO	
			V7 (WEEK 56)	380	10JAN2012	10:25	YES	NO	
	059	1	SCREENING	-2	27DEC2010	13:00	YES	NO	
			V1 (WEEK 0)	1	29DEC2010	10:05	YES	NO	
			V3 (WEEK 12)	93	31MAR2011	9:40	YES	NO	
			V4 (WEEK 24)	161	07JUN2011	9:00	YES	NO	
			V5 (WEEK 36)	254	08SEP2011	10:15	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	059	1	V6 (WEEK 52)	345	08DEC2011	10:00	YES	NO	
			V7 (WEEK 56)	380	12JAN2012	11:00	YES	NO	
	065	16	SCREENING	-20	10AUG2010	11:20	YES	NO	
			V1 (WEEK 0)	1	30AUG2010	9:05	YES	NO	
			V3 (WEEK 12)	85	22NOV2010	10:50	YES	NO	
			V4 (WEEK 24)	141	17JAN2011	11:50	YES	NO	
	068	16	SCREENING	-27	26OCT2010	8:55	YES	NO	
			V1 (WEEK 0)	1	22NOV2010	10:10	YES	NO	
			V3 (WEEK 12)	81	14FEB2011	9:00	YES	NO	
			V4 (WEEK 24)	163	03MAY2011	10:30	YES	NO	
			V5 (WEEK 36)	262	10AUG2011	9:10	YES	NO	
			V6 (WEEK 52)	372	28NOV2011	10:30	YES	NO	
			V7 (WEEK 56)	414	09JAN2012	11:45	YES	NO	
	069	23	SCREENING	-13	24NOV2010	9:42	YES	NO	
			V1 (WEEK 0)	1	07DEC2010	12:30	YES	NO	
			V3 (WEEK 12)	93	09MAR2011	12:20	YES	NO	
			V4 (WEEK 24)	164	19MAY2011	9:30	YES	NO	
			V5 (WEEK 36)	261	24AUG2011	11:00	YES	NO	
			V6 (WEEK 52)	373	14DEC2011	9:00	YES	NO	
			V7 (WEEK 56)	401	11JAN2012	9:00	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	072	18	SCREENING	-20	01DEC2010	11:10	YES	NO	
			V1 (WEEK 0)	1	21DEC2010	12:15	YES	NO	
			V3 (WEEK 12)	85	15MAR2011	9:55	YES	NO	
			V4 (WEEK 24)	169	07JUN2011	10:01	YES	NO	
			V5 (WEEK 36)	262	08SEP2011	11:03	YES	NO	
			V6 (WEEK 52)	360	15DEC2011	9:59	YES	NO	
			V7 (WEEK 56)	393	17JAN2012	9:27	YES	NO	
	079	13	SCREENING	-18	19JUL2010	15:00	YES	NO	
			V1 (WEEK 0)	1	06AUG2010	9:50	YES	NO	
			V3 (WEEK 12)	96	09NOV2010	11:40	YES	NO	
			V4 (WEEK 24)	175	27JAN2011	13:00	YES	NO	
			V5 (WEEK 36)	249	11APR2011	11:45	YES	NO	
			V6 (WEEK 52)	320	21JUN2011	11:15	YES	NO	
			V7 (WEEK 56)	348	19JUL2011	14:35	YES	NO	
	082	17	SCREENING	-8	06OCT2010	11:00	YES	NO	
			V1 (WEEK 0)	1	14OCT2010	9:00	YES	NO	
			V3 (WEEK 12)	84	05JAN2011	12:30	YES	NO	
			V4 (WEEK 24)	175	06APR2011	9:20	YES	NO	
			V5 (WEEK 36)	252	22JUN2011	11:15	YES	NO	
			V6 (WEEK 52)	364	12OCT2011	9:15	YES	NO	
			V7 (WEEK 56)	407	24NOV2011	9:20	YES	NO	

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Listing 16.2.8.1.1: Assessment of laboratory values (blood)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	084	17	SCREENING	-9	08NOV2010	10:00	YES	NO	
			V1 (WEEK 0)	1	17NOV2010	9:15	YES	NO	
			V3 (WEEK 12)	84	08FEB2011	10:20	YES	NO	
			V4 (WEEK 24)	175	10MAY2011	10:45	YES	NO	
			V5 (WEEK 36)	259	02AUG2011	11:15	YES	NO	
			V6 (WEEK 52)	371	22NOV2011	11:30	YES	NO	
			V7 (WEEK 56)	394	15DEC2011	9:32	YES	NO	
	086	21	SCREENING	-24	04OCT2010	11:05	YES	NO	
			V1 (WEEK 0)	1	28OCT2010	14:05	YES	NO	
			V3 (WEEK 12)	83	18JAN2011	11:30	YES	NO	
			V4 (WEEK 24)	167	12APR2011	11:55	YES	NO	
			V5 (WEEK 36)	251	05JUL2011	11:57	YES	NO	
			V6 (WEEK 52)	363	25OCT2011	11:30	YES	NO	
			V7 (WEEK 56)	391	22NOV2011	10:10	YES	NO	
	088	16	SCREENING	-9	30NOV2010	10:00	YES	NO	
			V1 (WEEK 0)	1	09DEC2010	9:05	YES	NO	
			V3 (WEEK 12)	83	01MAR2011	10:00	YES	NO	
			V4 (WEEK 24)	162	19MAY2011	9:30	YES	NO	
			V5 (WEEK 36)	264	29AUG2011	9:35	YES	NO	
			V6 (WEEK 52)	404	16JAN2012	9:30	YES	NO	
			V7 (WEEK 56)	404	16JAN2012	9:30	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	002	1	SCREENING	-7	16APR2009	10:00	YES	NO	
			V1 (WEEK 0)	1	23APR2009	8:55	YES	NO	
			V2 (WEEK 4)	28	20MAY2009	9:30			
			V3 (WEEK 12)	85	16JUL2009	8:30	YES	NO	
			V4 (WEEK 24)	169	08OCT2009	10:35	YES	NO	
			V5 (WEEK 36)	258	05JAN2010	10:20			
			V6 (WEEK 52)	365	22APR2010	10:10	YES	NO	
			V7 (WEEK 56)	393	20MAY2010	9:15			
	004	1	SCREENING	-29	17JUN2009	11:40	YES	NO	
			V1 (WEEK 0)	1	16JUL2009	10:00	YES	NO	
			V3 (WEEK 12)	92	15OCT2009	14:50	YES	NO	
	006	2	SCREENING	-32	25JAN2010	8:30	YES	NO	
			V1 (WEEK 0)	1	26FEB2010	9:00	YES	NO	
			V3 (WEEK 12)	85	21MAY2010	9:15	YES	NO	
			V4 (WEEK 24)	169	13AUG2010	9:15	YES	NO	
			V6 (WEEK 52)	364	24FEB2011	8:25	YES	NO	
			V7 (WEEK 56)	390	22MAR2011	8:45			
	010	1	SCREENING	-26	25JUN2009	9:45	YES	NO	
			V1 (WEEK 0)	1	21JUL2009	11:00	YES	NO	
			V3 (WEEK 12)	85	13OCT2009	10:45	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	002	1	SCREENING	-7		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	28	NEGATIVE	
			V3 (WEEK 12)	85	NEGATIVE	
			V4 (WEEK 24)	169	NEGATIVE	
			V5 (WEEK 36)	258	NEGATIVE	
			V6 (WEEK 52)	365	NEGATIVE	
			V7 (WEEK 56)	393		
	004	1	SCREENING	-29		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	92		
	006	2	SCREENING	-32		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	85		
			V4 (WEEK 24)	169		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	390		
	010	1	SCREENING	-26		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	85		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	012	1	SCREENING	-32	17JUN2010	12:20	YES	NO	
			V1 (WEEK 0)	1	19JUL2010	10:00	YES	NO	
			V3 (WEEK 12)	88	14OCT2010	9:15	YES	NO	
			V6 (WEEK 52)	361	14JUL2011	10:25	YES	NO	
			V7 (WEEK 56)	396	18AUG2011	12:15			
	014	4	SCREENING	-26	07OCT2009	13:45	YES	NO	
			V1 (WEEK 0)	1	02NOV2009	10:00	YES	NO	
			V3 (WEEK 12)	85	25JAN2010	11:00	YES	NO	
			V4 (WEEK 24)	172	22APR2010	10:20	YES	YES	PROTEINURIA OF 250 MG/L, GP IS INFORMED
			V6 (WEEK 52)	361	28OCT2010	13:30	YES	NO	
			V7 (WEEK 56)	396	02DEC2010	11:35			
	015	4	SCREENING	-32	21JAN2010	12:15	YES	NO	
			V1 (WEEK 0)	1	22FEB2010	11:45	YES	NO	
			V2 (WEEK 4)	29	22MAR2010	10:00			
			V3 (WEEK 12)	85	17MAY2010	10:30	YES	NO	
			V4 (WEEK 24)	162	02AUG2010	9:40	YES	NO	
			V5 (WEEK 36)	248	27OCT2010	11:15			
			V6 (WEEK 52)	365	21FEB2011	12:30	YES	NO	
			V7 (WEEK 56)	394	22MAR2011	11:00			
	017	5	SCREENING	-22	14JUL2009	10:30	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	012	1	SCREENING	-32		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	88		
			V6 (WEEK 52)	361		
			V7 (WEEK 56)	396		
	014	4	SCREENING	-26		
			V1 (WEEK 0)	1	NOT DONE	MALE PATIENT
			V3 (WEEK 12)	85	NOT DONE	MALE PATIENT
			V4 (WEEK 24)	172		
			V6 (WEEK 52)	361		
			V7 (WEEK 56)	396		
	015	4	SCREENING	-32		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	29	NEGATIVE	
			V3 (WEEK 12)	85	NEGATIVE	
			V4 (WEEK 24)	162	NEGATIVE	
			V5 (WEEK 36)	248	NEGATIVE	
			V6 (WEEK 52)	365	NEGATIVE	
			V7 (WEEK 56)	394		
	017	5	SCREENING	-22		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	017	5	V1 (WEEK 0)	1	05AUG2009	9:10	YES	NO	
			V3 (WEEK 12)	85	28OCT2009	8:45	YES	NO	
			V4 (WEEK 24)	169	20JAN2010	9:00	YES	NO	
			V5 (WEEK 36)	252	13APR2010	10:45			
			V6 (WEEK 52)	364	03AUG2010	11:00	YES	NO	
			V7 (WEEK 56)	392	31AUG2010	9:00			
	019	5	SCREENING	-21	18NOV2009	12:55	YES	NO	
			V1 (WEEK 0)	1	09DEC2009	9:00	YES	NO	
			V3 (WEEK 12)	85	03MAR2010	9:00	YES	NO	
			V4 (WEEK 24)	168	25MAY2010	9:00	YES	NO	
			V6 (WEEK 52)	364	07DEC2010	9:00	YES	NO	
			V7 (WEEK 56)	399	11JAN2011	9:15			
	023	4	SCREENING	-19	01JUL2010	13:15	YES	NO	
			V1 (WEEK 0)	1	20JUL2010	11:30	YES	NO	
			V3 (WEEK 12)	86	13OCT2010	9:45	YES	NO	
			V4 (WEEK 24)	177	12JAN2011	13:00	YES	NO	
			V5 (WEEK 36)	245	21MAR2011	10:00			
			V6 (WEEK 52)	364	18JUL2011	10:10	YES	NO	
			V7 (WEEK 56)	388	11AUG2011	12:45			
	027	20	SCREENING	-21	30SEP2010	10:40	YES	NO	
			V1 (WEEK 0)	1	21OCT2010	9:15	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	017	5	V1 (WEEK 0)	1		
			V3 (WEEK 12)	85		
			V4 (WEEK 24)	169		
			V5 (WEEK 36)	252		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	392		
	019	5	SCREENING	-21		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	85		
			V4 (WEEK 24)	168		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	399		
	023	4	SCREENING	-19		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	86		
			V4 (WEEK 24)	177		
			V5 (WEEK 36)	245		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	388		
	027	20	SCREENING	-21		
			V1 (WEEK 0)	1	NEGATIVE	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	027	20	V3 (WEEK 12)	92	20JAN2011	11:15	YES	NO	
			V4 (WEEK 24)	174	12APR2011	10:35	YES	YES	E.G. LEUCOCYTES, ERYTHROCYTES
			V5 (WEEK 36)	259	06JUL2011	9:30			
			V6 (WEEK 52)	370	25OCT2011	8:25	YES	YES	URINARY TRACT INFECTION
			V7 (WEEK 56)	407	01DEC2011	10:15			
	030	8	SCREENING	-7	18MAR2010	13:30	YES	NO	
			V1 (WEEK 0)	1	25MAR2010	11:30	YES	NO	
			V3 (WEEK 12)	85	17JUN2010	10:35	YES	YES	LEUCOS 25/UL / BACTERIA +++
			V4 (WEEK 24)	163	03SEP2010	11:45	YES	NO	
			V6 (WEEK 52)	355	14MAR2011	14:00	YES	YES	LEUCO'S 100/??L_ BACTERIA +++/HPF
			V7 (WEEK 56)	383	11APR2011	11:35			
	032	8	SCREENING	-10	08NOV2010	11:40	YES	NO	
			V1 (WEEK 0)	1	18NOV2010	15:00	YES	NO	
			V3 (WEEK 12)	82	07FEB2011	12:30	YES	NO	
	033	9	SCREENING	-7	28OCT2009	11:30	YES	NO	
			V1 (WEEK 0)	1	04NOV2009	8:20	YES	NO	
			V3 (WEEK 12)	78	20JAN2010	9:10	YES	NO	
			V4 (WEEK 24)	169	21APR2010	9:30	YES	NO	
			V5 (WEEK 36)	261	22JUL2010	8:45			
			V6 (WEEK 52)	372	10NOV2010	8:20	YES	NO	
			V7 (WEEK 56)	398	06DEC2010	8:35			

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	027	20	V3 (WEEK 12)	92		
			V4 (WEEK 24)	174		
			V5 (WEEK 36)	259		
			V6 (WEEK 52)	370		
			V7 (WEEK 56)	407		
	030	8	SCREENING	-7		
			V1 (WEEK 0)	1	NOT DONE	POSTMENOPAUSAL
			V3 (WEEK 12)	85	NOT DONE	POSTMENOPAUSAL
			V4 (WEEK 24)	163		
			V6 (WEEK 52)	355	NOT DONE	POSTMENOPAUSAL
			V7 (WEEK 56)	383		
	032	8	SCREENING	-10		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	82		
	033	9	SCREENING	-7		
			V1 (WEEK 0)	1	NOT DONE	POSTMENOPAUSAL LONGER THAN 2 YEARS
			V3 (WEEK 12)	78	NOT DONE	POST MENOPAUSAL
			V4 (WEEK 24)	169	NOT DONE	POST MENOPAUSAL
			V5 (WEEK 36)	261	NOT DONE	POSTMENOPAUSAL
			V6 (WEEK 52)	372	NOT DONE	POSTMENOPAUSAL
			V7 (WEEK 56)	398		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	042	12	SCREENING	-29	16DEC2009	9:45	YES	NO	
			V1 (WEEK 0)	1	14JAN2010	9:45	YES	NO	
			V2 (WEEK 4)	29	11FEB2010	10:00			
			V3 (WEEK 12)	126	19MAY2010	9:00	YES	NO	
			V4 (WEEK 24)	168	30JUN2010	12:45	YES	NO	
			V5 (WEEK 36)	252	22SEP2010	9:05			
			V6 (WEEK 52)	364	12JAN2011	13:00	YES	NO	
			V7 (WEEK 56)	391	08FEB2011	9:30			
	043	12	SCREENING	-28	21OCT2009	9:45	YES	NO	
			V1 (WEEK 0)	1	18NOV2009	13:45	YES	NO	
			V3 (WEEK 12)	85	10FEB2010	12:00	YES	NO	
			V4 (WEEK 24)	176	12MAY2010	13:00	YES	NO	
	046	11	SCREENING	-28	14DEC2009	10:00	YES	YES	ELEVATED PROTEIN
			V1 (WEEK 0)	1	11JAN2010	12:00	YES	NO	
			V3 (WEEK 12)	87	07APR2010	11:30	YES	NO	
			V4 (WEEK 24)	178	07JUL2010	11:00	YES	NO	
			V6 (WEEK 52)	367	12JAN2011	9:30	YES	NO	
			V7 (WEEK 56)	393	07FEB2011	9:00			
	048	11	SCREENING	-5	17NOV2010	12:30	YES	NO	
			V1 (WEEK 0)	1	22NOV2010	10:35	YES	NO	
			V3 (WEEK 12)	86	15FEB2011	12:00	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	042	12	SCREENING	-29		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	29		
			V3 (WEEK 12)	126	NEGATIVE	
			V4 (WEEK 24)	168	NEGATIVE	
			V5 (WEEK 36)	252	NEGATIVE	
			V6 (WEEK 52)	364	NEGATIVE	
			V7 (WEEK 56)	391		
	043	12	SCREENING	-28		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	85		
			V4 (WEEK 24)	176		
	046	11	SCREENING	-28		
			V1 (WEEK 0)	1	NOT DONE	PATIENT POST MENOPAUSIS
			V3 (WEEK 12)	87	NOT DONE	PATIENT POST MENOPAUSIS
			V4 (WEEK 24)	178	NOT DONE	PATIENT POST MENOPAUSIS
			V6 (WEEK 52)	367	NOT DONE	POST MENOPAUSAL
			V7 (WEEK 56)	393		
	048	11	SCREENING	-5		
			V1 (WEEK 0)	1	NOT DONE	MALE PATIENT
			V3 (WEEK 12)	86	NOT DONE	MALE PATIENT

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	048	11	V4 (WEEK 24)	176	16MAY2011	11:30	YES	NO	
			V5 (WEEK 36)	247	26JUL2011	10:55			
			V6 (WEEK 52)	360	16NOV2011	10:10	YES	NO	
			V7 (WEEK 56)	395	21DEC2011	11:35			
	050	21	SCREENING	-51	06SEP2010	14:30	YES	NO	
			UNSCHEDULED	211	25MAY2011	9:30	YES	NO	
			V1 (WEEK 0)	1	27OCT2010	11:45	YES	NO	
			V3 (WEEK 12)	83	17JAN2011	11:15	YES	NO	
			V4 (WEEK 24)	167	11APR2011	11:20	YES	NO	
			V5 (WEEK 36)	251	04JUL2011	11:50			
			V6 (WEEK 52)	363	24OCT2011	10:45	YES	NO	
			V7 (WEEK 56)	391	21NOV2011	9:30			
	052	21	SCREENING	-52	06SEP2010	14:15	YES	NO	
			V1 (WEEK 0)	1	28OCT2010	8:15	YES	NO	
			V3 (WEEK 12)	82	17JAN2011	10:45	YES	NO	
			V4 (WEEK 24)	166	11APR2011	10:40	YES	NO	
			V5 (WEEK 36)	250	04JUL2011	9:24			
			V6 (WEEK 52)	362	24OCT2011	14:45	YES	NO	
			V7 (WEEK 56)	390	21NOV2011	11:45			
	055	5	SCREENING	-21	08MAR2010	11:30	YES	NO	
			V1 (WEEK 0)	1	29MAR2010	9:30	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	048	11	V4 (WEEK 24)	176	NOT DONE	MALE PATIENT
			V5 (WEEK 36)	247	NOT DONE	MALE PATIENT
			V6 (WEEK 52)	360	NOT DONE	MALE PATIENT
			V7 (WEEK 56)	395		
	050	21	SCREENING	-51		
			UNSCHEDULED	211		PATIENT IS POSTMENOPAUSAL
			V1 (WEEK 0)	1	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V3 (WEEK 12)	83	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V4 (WEEK 24)	167	NOT DONE	POSTMENOPAUSAL
			V5 (WEEK 36)	251	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V6 (WEEK 52)	363	NOT DONE	N/A
			V7 (WEEK 56)	391		
	052	21	SCREENING	-52		
			V1 (WEEK 0)	1	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V3 (WEEK 12)	82	NOT DONE	POSTMENOPAUSAL
			V4 (WEEK 24)	166	NOT DONE	POSTMENOPAUSAL
			V5 (WEEK 36)	250	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V6 (WEEK 52)	362	NOT DONE	N/A
			V7 (WEEK 56)	390		
	055	5	SCREENING	-21		
			V1 (WEEK 0)	1		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	055	5	V6 (WEEK 52)	30	27APR2010	9:15	YES	NO	
	057	1	SCREENING	-21	29JUL2010	10:50	YES	NO	
			V1 (WEEK 0)	1	19AUG2010	11:10	YES	NO	
			V2 (WEEK 4)	33	20SEP2010	9:55			
			V3 (WEEK 12)	82	08NOV2010	10:00	YES	NO	
			V4 (WEEK 24)	170	04FEB2011	9:35	YES	NO	
	066	16	SCREENING	-31	09AUG2010	10:50	YES	NO	
			V1 (WEEK 0)	1	09SEP2010	9:30	YES	NO	
			V3 (WEEK 12)	83	30NOV2010	9:30	YES	NO	
	067	16	SCREENING	-16	02NOV2010	10:00	YES	NO	
			V1 (WEEK 0)	1	18NOV2010	9:00	YES	NO	
			V7 (WEEK 56)	111	08MAR2011	9:15			
	071	18	SCREENING	-20	20OCT2010	10:10	YES	NO	
			V1 (WEEK 0)	1	09NOV2010	10:45	YES	NO	
			V3 (WEEK 12)	87	03FEB2011	10:12	YES	NO	
			V4 (WEEK 24)	177	04MAY2011	9:30	YES	NO	
			V5 (WEEK 36)	253	19JUL2011	11:03			
			V6 (WEEK 52)	374	17NOV2011	13:00	YES	NO	
			V7 (WEEK 56)	392	05DEC2011	11:40			

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	055	5	V6 (WEEK 52)	30		
	057	1	SCREENING	-21		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	33	NEGATIVE	
			V3 (WEEK 12)	82		
			V4 (WEEK 24)	170		
	066	16	SCREENING	-31		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	83		
	067	16	SCREENING	-16		
			V1 (WEEK 0)	1	NOT DONE	MENOPAUSE SINCE 2001
			V7 (WEEK 56)	111		
	071	18	SCREENING	-20		
			V1 (WEEK 0)	1	NOT DONE	POSTMENOPAUSAL SINCE 1998
			V3 (WEEK 12)	87		
			V4 (WEEK 24)	177		
			V5 (WEEK 36)	253		
			V6 (WEEK 52)	374		
			V7 (WEEK 56)	392		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	080	13	SCREENING	-10	08NOV2010	10:51	YES	NO	LEUKOZYTEN 100/MICROL
			UNSCHEDULED	42	29DEC2010	14:50	YES	YES	
			V1 (WEEK 0)	1	18NOV2010	12:35	YES	NO	
			V2 (WEEK 4)	26	13DEC2010	10:20			
			V3 (WEEK 12)	84	09FEB2011	12:20	YES	NO	
			V6 (WEEK 52)	196	01JUN2011	13:00	YES	NO	
	081	17	SCREENING	-10	04OCT2010	12:00	YES	NO	
			V3 (WEEK 12)	89	10JAN2011	12:01	YES	NO	
			V4 (WEEK 24)	175	06APR2011	11:50	YES	NO	
			V6 (WEEK 52)	376	24OCT2011	12:00	YES	NO	
			V7 (WEEK 56)	405	22NOV2011	12:00			
	083	17	SCREENING	-15	26OCT2010	12:30	YES	NO	
			V1 (WEEK 0)	1	10NOV2010	10:15	YES	NO	
			V4 (WEEK 24)	168	26APR2011	11:05	YES	NO	
			V5 (WEEK 36)	258	25JUL2011	10:20			
			V6 (WEEK 52)	365	09NOV2011	12:00	YES	NO	
			V7 (WEEK 56)	392	06DEC2011	12:00			
	087	16	SCREENING	-20	09NOV2010	9:25	YES	NO	
			V3 (WEEK 12)	81	17FEB2011	10:00	YES	NO	
			V4 (WEEK 24)	169	16MAY2011	11:05	YES	NO	
			V5 (WEEK 36)	255	10AUG2011	11:00			

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	080	13	SCREENING	-10		
			UNSCHEDULED	42		PATIENT SURGICALLY STERILIZED
			V1 (WEEK 0)	1	NOT DONE	STERILIZED
			V2 (WEEK 4)	26	NEGATIVE	
			V3 (WEEK 12)	84		
			V6 (WEEK 52)	196		
	081	17	SCREENING	-10		
			V3 (WEEK 12)	89		
			V4 (WEEK 24)	175		
			V6 (WEEK 52)	376		
			V7 (WEEK 56)	405		
	083	17	SCREENING	-15		
			V1 (WEEK 0)	1		
			V4 (WEEK 24)	168		
			V5 (WEEK 36)	258		
			V6 (WEEK 52)	365		
			V7 (WEEK 56)	392		
	087	16	SCREENING	-20		
			V3 (WEEK 12)	81	NOT DONE	POSTMENOPAUSAL
			V4 (WEEK 24)	169	NOT DONE	POSTMENOPAUSAL SINCE 2000
			V5 (WEEK 36)	255	NOT DONE	PATIENT IS A MALE

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
ACI-91	087	16	V6 (WEEK 52)	365	28NOV2011	10:00	YES	NO	
			V7 (WEEK 56)	395	28DEC2011	11:45			
	089	5	SCREENING	-28	20OCT2010	10:00	YES	NO	
			V1 (WEEK 0)	1	16NOV2010	11:45	YES	NO	
			V3 (WEEK 12)	84	08FEB2011	8:30	YES	NO	
			V6 (WEEK 52)	364	14NOV2011	12:15	YES	YES	LEUCOCYTES, ERYTHROCYTES, BACTERIA. ROUND EPITHELIAL CELLS
	093	17	SCREENING	-3	29NOV2010	12:25	YES	NO	
			V1 (WEEK 0)	1	02DEC2010	9:25	YES	NO	
			V3 (WEEK 12)	86	25FEB2011	11:15	YES	NO	
			V4 (WEEK 24)	173	23MAY2011	12:31	YES	NO	
			V6 (WEEK 52)	370	06DEC2011	11:00	YES	NO	
			V7 (WEEK 56)	392	28DEC2011	12:00			
	097	12	SCREENING	-21	27OCT2010	8:50	YES	NO	
			V1 (WEEK 0)	1	17NOV2010	9:00	YES	NO	
			V2 (WEEK 4)	28	14DEC2010	9:00			
			V3 (WEEK 12)	85	09FEB2011	13:00	YES	NO	
Placebo	001	1	SCREENING	-7	02APR2009	10:45	YES	NO	
			V1 (WEEK 0)	1	09APR2009	10:30	YES	NO	
			V2 (WEEK 4)	29	07MAY2009	10:00			

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
ACI-91	087	16	V6 (WEEK 52)	365	NOT DONE	MENOPAUSE
			V7 (WEEK 56)	395		
	089	5	SCREENING	-28		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	84		
			V6 (WEEK 52)	364		
	093	17	SCREENING	-3		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	86		
			V4 (WEEK 24)	173		
			V6 (WEEK 52)	370		
			V7 (WEEK 56)	392		
	097	12	SCREENING	-21		
			V1 (WEEK 0)	1		
			V2 (WEEK 4)	28		
			V3 (WEEK 12)	85		
Placebo	001	1	SCREENING	-7		
			V1 (WEEK 0)	1		NEGATIVE
			V2 (WEEK 4)	29		NEGATIVE

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	001	1	V3 (WEEK 12)	90	07JUL2009	8:55	YES	NO	
			V4 (WEEK 24)	162	17SEP2009	11:00	YES	NO	
			V5 (WEEK 36)	246	10DEC2009	9:10			
			V6 (WEEK 52)	365	08APR2010	9:00	YES	NO	
			V7 (WEEK 56)	393	06MAY2010	13:20			
	003	1	SCREENING	-21	07MAY2009	10:10	YES	NO	
			V1 (WEEK 0)	1	28MAY2009	11:25	YES	NO	
			V2 (WEEK 4)	28	24JUN2009	9:15			
			V3 (WEEK 12)	90	25AUG2009	11:50	YES	NO	
			V4 (WEEK 24)	169	12NOV2009	10:20	YES	NO	
	005	2	SCREENING	-16	19MAY2009	16:25	YES	NO	
			V1 (WEEK 0)	1	04JUN2009	8:40	YES	NO	
			V2 (WEEK 4)	27	30JUN2009	9:05			
			V3 (WEEK 12)	83	25AUG2009	8:30	YES	NO	
			V4 (WEEK 24)	168	18NOV2009	10:05	YES	NO	
			V6 (WEEK 52)	364	02JUN2010	9:15	YES	NO	
			V7 (WEEK 56)	400	08JUL2010	9:00			
	009	1	SCREENING	-33	06AUG2009	11:40	YES	NO	
			V1 (WEEK 0)	1	08SEP2009	9:10	YES	NO	
			V2 (WEEK 4)	30	07OCT2009	10:20			
			V3 (WEEK 12)	94	10DEC2009	9:40	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	001	1	V3 (WEEK 12)	90	NEGATIVE	
			V4 (WEEK 24)	162	NEGATIVE	
			V5 (WEEK 36)	246	NEGATIVE	
			V6 (WEEK 52)	365	NEGATIVE	
			V7 (WEEK 56)	393		
	003	1	SCREENING	-21		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	28	NEGATIVE	
			V3 (WEEK 12)	90	NEGATIVE	
			V4 (WEEK 24)	169	NEGATIVE	
	005	2	SCREENING	-16		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	27	NEGATIVE	
			V3 (WEEK 12)	83	NEGATIVE	
			V4 (WEEK 24)	168		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	400		
	009	1	SCREENING	-33		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	30	NEGATIVE	
			V3 (WEEK 12)	94	NEGATIVE	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	009	1	V4 (WEEK 24)	178	04MAR2010	12:50	YES	NO	
			V5 (WEEK 36)	246	11MAY2010	10:20			
			V6 (WEEK 52)	361	03SEP2010	10:15	YES	NO	
			V7 (WEEK 56)	389	01OCT2010	9:00			
	011	1	SCREENING	-21	05NOV2009	13:10	YES	NO	
			V1 (WEEK 0)	1	26NOV2009	10:25	YES	NO	
			V2 (WEEK 4)	35	30DEC2009	13:40			
			V3 (WEEK 12)	85	18FEB2010	9:00	YES	NO	
			V4 (WEEK 24)	162	06MAY2010	13:25	YES	NO	
			V5 (WEEK 36)	253	05AUG2010	12:10			
			V6 (WEEK 52)	366	26NOV2010	10:15	YES	NO	
			V7 (WEEK 56)	397	27DEC2010	12:30			
	013	4	SCREENING	-30	17AUG2009	10:00	YES	NO	
			V1 (WEEK 0)	1	16SEP2009	12:00	YES	NO	
			V2 (WEEK 4)	29	14OCT2009	10:30			
			V3 (WEEK 12)	85	09DEC2009	11:45	YES	NO	
			V4 (WEEK 24)	170	04MAR2010	11:30	YES	NO	
			V5 (WEEK 36)	247	20MAY2010	10:30			
			V6 (WEEK 52)	366	16SEP2010	11:15	YES	NO	
			V7 (WEEK 56)	400	20OCT2010	12:45			

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	009	1	V4 (WEEK 24)	178	NEGATIVE	
			V5 (WEEK 36)	246	NEGATIVE	
			V6 (WEEK 52)	361	NEGATIVE	
			V7 (WEEK 56)	389		
	011	1	SCREENING	-21		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	35	NEGATIVE	
			V3 (WEEK 12)	85	NEGATIVE	
			V4 (WEEK 24)	162	NEGATIVE	
			V5 (WEEK 36)	253	NEGATIVE	
			V6 (WEEK 52)	366	NEGATIVE	
			V7 (WEEK 56)	397		
	013	4	SCREENING	-30		
			V1 (WEEK 0)	1	NOT DONE	PATIENT IS MENOPAUSAL SINCE > 25 YEARS. PREGANCY TESTS WERE NOT DELIVERED.
			V2 (WEEK 4)	29	NEGATIVE	
			V3 (WEEK 12)	85	NEGATIVE	
			V4 (WEEK 24)	170	NEGATIVE	
			V5 (WEEK 36)	247	NEGATIVE	
			V6 (WEEK 52)	366	NEGATIVE	
			V7 (WEEK 56)	400		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	016	4	SCREENING	-28	01FEB2010	12:00	YES	NO	
			V1 (WEEK 0)	1	01MAR2010	12:00	YES	NO	
			V3 (WEEK 12)	80	19MAY2010	10:30	YES	NO	
			V4 (WEEK 24)	162	09AUG2010	12:15	YES	NO	
			V6 (WEEK 52)	365	28FEB2011	11:00	YES	NO	
			V7 (WEEK 56)	403	07APR2011	11:30			
	018	5	SCREENING	-20	03NOV2009	13:15	YES	NO	
			V1 (WEEK 0)	1	23NOV2009	13:00	YES	NO	
			V3 (WEEK 12)	86	16FEB2010	12:45	YES	NO	
			V4 (WEEK 24)	170	11MAY2010	9:00	YES	NO	
			V6 (WEEK 52)	366	23NOV2010	9:20	YES	NO	
			V7 (WEEK 56)	387	14DEC2010	8:50			
	020	5	SCREENING	-26	27JAN2010	15:30	YES	NO	
			V1 (WEEK 0)	1	22FEB2010	13:10	YES	NO	
	024	4	SCREENING	-31	16JUL2010	12:00	YES	YES	BACTERIA IN URINE, CONTROL ON VISIT 1
			V1 (WEEK 0)	1	16AUG2010	11:30	YES	NO	
			V3 (WEEK 12)	87	10NOV2010	10:25	YES	NO	
			V4 (WEEK 24)	171	02FEB2011	11:45	YES	NO	
			V5 (WEEK 36)	246	18APR2011	10:15			
			V6 (WEEK 52)	358	08AUG2011	13:00	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	016	4	SCREENING	-28		
			V1 (WEEK 0)	1	NOT DONE	MALE PATIENT
			V3 (WEEK 12)	80		
			V4 (WEEK 24)	162		
			V6 (WEEK 52)	365		
			V7 (WEEK 56)	403		
	018	5	SCREENING	-20		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	86		
			V4 (WEEK 24)	170		
			V6 (WEEK 52)	366		
			V7 (WEEK 56)	387		
	020	5	SCREENING	-26		
			V1 (WEEK 0)	1		
	024	4	SCREENING	-31		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	87		
			V4 (WEEK 24)	171		
			V5 (WEEK 36)	246		
			V6 (WEEK 52)	358		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	024	4	V7 (WEEK 56)	393	12SEP2011	12:50			
	028	20	SCREENING	-8	18NOV2010	10:20	YES	NO	
			V1 (WEEK 0)	1	26NOV2010	9:20	YES	NO	
			V3 (WEEK 12)	89	22FEB2011	10:25	YES	YES	LEUCOCYTES, BACTERIA, ERYTHROCYTES, E.T.C
			V4 (WEEK 24)	180	24MAY2011	10:15	YES	NO	
			V5 (WEEK 36)	273	25AUG2011	10:45			
			V6 (WEEK 52)	364	24NOV2011	10:30	YES	NO	
			V7 (WEEK 56)	390	20DEC2011	10:16			
	029	8	SCREENING	-3	26JAN2010	10:30	YES	NO	
			V1 (WEEK 0)	1	29JAN2010	15:00	YES	YES	LEUCOCYTES 25/
			V3 (WEEK 12)	82	20APR2010	11:00	YES	NO	
			V4 (WEEK 24)	158	05JUL2010	10:30	YES	YES	LEUCO 100 / µL SEE COMMENT
			V6 (WEEK 52)	369	01FEB2011	10:45	YES	YES	STATUS LEUCOS 25/??L SEDIMENT: LEUCOS 7-10/HPF
			V7 (WEEK 56)	391	23FEB2011	12:00			
	031	8	SCREENING	-14	06MAY2010	14:00	YES	NO	
			V1 (WEEK 0)	1	20MAY2010	11:00	YES	NO	
			V3 (WEEK 12)	90	17AUG2010	11:40	YES	NO	
			V4 (WEEK 24)	174	09NOV2010	11:40	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	024	4	V7 (WEEK 56)	393		
	028	20	SCREENING	-8		
			V1 (WEEK 0)	1	NEGATIVE	
			V3 (WEEK 12)	89	NOT DONE	AGE
			V4 (WEEK 24)	180		
			V5 (WEEK 36)	273		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	390		
	029	8	SCREENING	-3		
			V1 (WEEK 0)	1	NOT DONE	SURGICAL STERIL
			V3 (WEEK 12)	82	NOT DONE	SURGICAL STERIL
			V4 (WEEK 24)	158	NOT DONE	SURGICAL STERIL
			V6 (WEEK 52)	369	NOT DONE	SURGICAL STERIL
			V7 (WEEK 56)	391		
	031	8	SCREENING	-14		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	90		
			V4 (WEEK 24)	174		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	031	8	V6 (WEEK 52)	363	17MAY2011	13:00	YES	NO	
			V7 (WEEK 56)	391	14JUN2011	10:20			
	034	9	SCREENING	-22	24FEB2010	8:50	YES	NO	
			V1 (WEEK 0)	1	18MAR2010	9:00	YES		
			V3 (WEEK 12)	83	08JUN2010	9:30	YES		
			V4 (WEEK 24)	175	08SEP2010	8:35	YES		
			V5 (WEEK 36)	258	30NOV2010	8:10			
			V7 (WEEK 56)	399	20APR2011	8:40			
	041	12	SCREENING	-16	23SEP2009	11:00	YES	NO	
			V1 (WEEK 0)	1	09OCT2009	12:15	YES		
			V3 (WEEK 12)	89	05JAN2010	13:30	YES		
			V4 (WEEK 24)	167	24MAR2010	9:15	YES		
			V5 (WEEK 36)	251	16JUN2010	9:20			
			V6 (WEEK 52)	363	06OCT2010	8:45	YES		
			V7 (WEEK 56)	392	04NOV2010	8:35			
	044	12	SCREENING	-28	04NOV2009	13:00	YES	NO	
			V1 (WEEK 0)	1	02DEC2009	9:45	YES		
			V2 (WEEK 4)	37	07JAN2010	10:00			
			V3 (WEEK 12)	85	24FEB2010	9:30	YES		
			V4 (WEEK 24)	176	26MAY2010	13:00	YES		
			V5 (WEEK 36)	260	18AUG2010	8:35			

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	031	8	V6 (WEEK 52)	363		
			V7 (WEEK 56)	391		
	034	9	SCREENING	-22		
			V1 (WEEK 0)	1	NOT DONE	POSTMENOPAUSAL
			V3 (WEEK 12)	83	NOT DONE	POSTMENOPAUSAL
			V4 (WEEK 24)	175	NOT DONE	POSTMENOPAUSAL
			V5 (WEEK 36)	258	NOT DONE	POSTMENOPAUSAL
			V7 (WEEK 56)	399		
	041	12	SCREENING	-16		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	89		
			V4 (WEEK 24)	167		
			V5 (WEEK 36)	251		
			V6 (WEEK 52)	363		
			V7 (WEEK 56)	392		
	044	12	SCREENING	-28		
			V1 (WEEK 0)	1	NEGATIVE	
			V2 (WEEK 4)	37	NEGATIVE	
			V3 (WEEK 12)	85	NEGATIVE	
			V4 (WEEK 24)	176	NEGATIVE	
			V5 (WEEK 36)	260	NEGATIVE	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	044	12	V6 (WEEK 52)	365	01DEC2010	11:50	YES	NO	
			V7 (WEEK 56)	400	05JAN2011	13:10			
	045	11	SCREENING	-14	07DEC2009	9:45	YES	NO	
			V1 (WEEK 0)	1	21DEC2009	9:45	YES	NO	
			V3 (WEEK 12)	85	15MAR2010	8:30	YES	NO	
			V4 (WEEK 24)	169	07JUN2010	9:30	YES	NO	
			V5 (WEEK 36)	260	06SEP2010	10:15			
			V6 (WEEK 52)	360	15DEC2010	10:00	YES	NO	
			V7 (WEEK 56)	393	17JAN2011	9:50			
	047	11	SCREENING	-21	12JUL2010	8:30	YES	NO	
			V1 (WEEK 0)	1	02AUG2010	8:55	YES	NO	
			V3 (WEEK 12)	80	20OCT2010	11:50	YES	NO	
			V4 (WEEK 24)	162	10JAN2011	10:30	YES	NO	
			V6 (WEEK 52)	360	27JUL2011	7:40	YES	NO	
			V7 (WEEK 56)	393	29AUG2011	8:35			
	049	21	SCREENING	-51	06SEP2010	10:45	YES	NO	
			UNSCHEDULED	213	27MAY2011	9:48	YES	NO	
				258	11JUL2011	9:37	YES	NO	
				267	20JUL2011	8:00	YES	YES	ENTEROCOCCUS SP.
				274	27JUL2011	11:03	YES	NO	
				286	08AUG2011	8:00	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	044	12	V6 (WEEK 52) V7 (WEEK 56)	365 400	NEGATIVE	
	045	11	SCREENING V1 (WEEK 0) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52) V7 (WEEK 56)	-14 1 85 169 260 360 393	NOT DONE NOT DONE NOT DONE NOT DONE NOT DONE	MALE MALE PATIENT MALE PATIENT MALE PATIENT MALE PATIENT
	047	11	SCREENING V1 (WEEK 0) V3 (WEEK 12) V4 (WEEK 24) V6 (WEEK 52) V7 (WEEK 56)	-21 1 80 162 360 393	NOT DONE NOT DONE NOT DONE NOT DONE	MALE PATIENT MALE PATIENT MALE PATIENT MALE PATIENT
	049	21	SCREENING UNSCHEDULED	-51 213 258 267 274 286		N/A N/A

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	049	21	UNSCHEDULED	302	24AUG2011	11:16	YES	NO	
			V1 (WEEK 0)	1	27OCT2010	8:55	YES	NO	
			V3 (WEEK 12)	84	18JAN2011	10:30	YES	NO	
			V4 (WEEK 24)	168	12APR2011	11:00	YES	NO	
			V5 (WEEK 36)	252	05JUL2011	10:00			
	051	21	SCREENING	-52	06SEP2010	12:40	YES	NO	
			V1 (WEEK 0)	1	28OCT2010	11:30	YES	NO	
			V3 (WEEK 12)	97	01FEB2011	11:30	YES	NO	
			V4 (WEEK 24)	167	12APR2011	13:30	YES	NO	
			V5 (WEEK 36)	251	05JUL2011	13:42			
			V6 (WEEK 52)	363	25OCT2011	10:30	YES	NO	
			V7 (WEEK 56)	391	22NOV2011	9:35			
	056	5	SCREENING	-21	31MAR2010	10:00	YES	NO	
			V1 (WEEK 0)	1	21APR2010	9:15	YES	NO	
			V3 (WEEK 12)	84	13JUL2010	11:15	YES	NO	
			V4 (WEEK 24)	168	05OCT2010	9:15	YES	NO	
			V6 (WEEK 52)	364	19APR2011	8:05	YES	NO	
			V7 (WEEK 56)	393	18MAY2011	11:25			
	058	1	SCREENING	-21	06DEC2010	10:00	YES	NO	
			V1 (WEEK 0)	1	27DEC2010	11:15	YES	NO	
			V3 (WEEK 12)	93	29MAR2011	11:10	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	049	21	UNSCHEDULED	302		
			V1 (WEEK 0)	1	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V3 (WEEK 12)	84	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V4 (WEEK 24)	168	NOT DONE	POSTMENOPAUSAL
			V5 (WEEK 36)	252	NOT DONE	PATIENT IS POSTMENOPAUSAL
	051	21	SCREENING	-52		
			V1 (WEEK 0)	1	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V3 (WEEK 12)	97	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V4 (WEEK 24)	167	NOT DONE	POSTMENOPAUSAL
			V5 (WEEK 36)	251	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V6 (WEEK 52)	363	NOT DONE	N/A
			V7 (WEEK 56)	391		
	056	5	SCREENING	-21		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	84		PATIENT IS POST MENOPAUSAL
			V4 (WEEK 24)	168		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	393		
	058	1	SCREENING	-21		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	93		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	058	1	V4 (WEEK 24)	166	10JUN2011	10:15	YES	NO	
			V5 (WEEK 36)	260	12SEP2011	10:50			
			V6 (WEEK 52)	345	06DEC2011	9:10	YES	YES	ERYTHROCYTES, BAKTERIA
			V7 (WEEK 56)	380	10JAN2012	10:25			
	059	1	SCREENING	-2	27DEC2010	13:00	YES	NO	
			V1 (WEEK 0)	1	29DEC2010	10:05	YES	NO	
			V3 (WEEK 12)	93	31MAR2011	9:40	YES	NO	
			V4 (WEEK 24)	161	07JUN2011	9:00	YES	NO	
			V6 (WEEK 52)	345	08DEC2011	10:05	YES	NO	
			V7 (WEEK 56)	380	12JAN2012	11:00			
	065	16	SCREENING	-20	10AUG2010	11:25	YES	NO	
			V1 (WEEK 0)	1	30AUG2010	9:00	YES	NO	
			V3 (WEEK 12)	85	22NOV2010	11:15	YES	NO	
			V4 (WEEK 24)	141	17JAN2011	12:00	YES	NO	
	068	16	SCREENING	-27	26OCT2010	9:05	YES	NO	
			V1 (WEEK 0)	1	22NOV2010	10:45	YES	NO	
			V3 (WEEK 12)	81	14FEB2011	9:30	YES	NO	
			V4 (WEEK 24)	163	03MAY2011	10:40	YES	NO	
			V5 (WEEK 36)	262	10AUG2011	9:30			
	069	23	SCREENING	-13	24NOV2010	12:30	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	058	1	V4 (WEEK 24)	166		
			V5 (WEEK 36)	260		
			V6 (WEEK 52)	345		
			V7 (WEEK 56)	380		
	059	1	SCREENING	-2		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	93		
			V4 (WEEK 24)	161		
			V6 (WEEK 52)	345		
			V7 (WEEK 56)	380		
	065	16	SCREENING	-20		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	85		
			V4 (WEEK 24)	141		
	068	16	SCREENING	-27		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	81		
			V4 (WEEK 24)	163		
			V5 (WEEK 36)	262	NOT DONE	PATIENT IS A MALE
	069	23	SCREENING	-13		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	069	23	V1 (WEEK 0)	1	07DEC2010	12:10	YES	NO	
			V3 (WEEK 12)	93	09MAR2011	12:20	YES	NO	
			V4 (WEEK 24)	164	19MAY2011	9:50	YES	NO	
			V5 (WEEK 36)	261	24AUG2011	11:10			
			V6 (WEEK 52)	373	14DEC2011	9:20	YES	NO	
			V7 (WEEK 56)	401	11JAN2012	10:00			
	072	18	SCREENING	-20	01DEC2010	12:45	YES	NO	
			V1 (WEEK 0)	1	21DEC2010	12:25	YES	NO	
			V3 (WEEK 12)	85	15MAR2011	11:10	YES	NO	
			V4 (WEEK 24)	169	07JUN2011	10:07	YES	NO	
			V5 (WEEK 36)	262	08SEP2011	12:10			
			V6 (WEEK 52)	360	15DEC2011	10:10	YES	NO	
			V7 (WEEK 56)	393	17JAN2012	10:24			
	079	13	SCREENING	-18	19JUL2010	15:03	YES	NO	
			V1 (WEEK 0)	1	06AUG2010	9:55	YES	NO	
			V3 (WEEK 12)	96	09NOV2010	12:10	YES	NO	
			V4 (WEEK 24)	175	27JAN2011	15:10	YES	NO	
			V6 (WEEK 52)	320	21JUN2011	11:20	YES	NO	
			V7 (WEEK 56)	348	19JUL2011	14:40			
	082	17	SCREENING	-8	06OCT2010	11:23	YES	NO	
			V3 (WEEK 12)	84	05JAN2011	12:45	YES	NO	

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	069	23	V1 (WEEK 0)	1	NOT DONE	PATIENT MALE!!
			V3 (WEEK 12)	93		
			V4 (WEEK 24)	164		
			V5 (WEEK 36)	261	NOT DONE	MALE!
			V6 (WEEK 52)	373		
			V7 (WEEK 56)	401		
	072	18	SCREENING	-20		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	85		
			V4 (WEEK 24)	169		
			V5 (WEEK 36)	262		
			V6 (WEEK 52)	360		
			V7 (WEEK 56)	393		
	079	13	SCREENING	-18		
			V1 (WEEK 0)	1	NOT DONE	POSTMENOPAUSAL
			V3 (WEEK 12)	96	NEGATIVE	
			V4 (WEEK 24)	175		
			V6 (WEEK 52)	320	NEGATIVE	
			V7 (WEEK 56)	348		
	082	17	SCREENING	-8		
			V3 (WEEK 12)	84		

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Result reviewed	Clinic. signif. finding	Specification
					Date	Time			
Placebo	082	17	V4 (WEEK 24)	175	06APR2011	9:31	YES	NO	
			V6 (WEEK 52)	364	12OCT2011	12:20	YES	NO	
			V7 (WEEK 56)	407	24NOV2011	10:00			
	084	17	SCREENING	-9	08NOV2010	9:50	YES	NO	
			V1 (WEEK 0)	1	17NOV2010	11:45	YES	NO	
			V3 (WEEK 12)	84	08FEB2011	12:05	YES	NO	
			V4 (WEEK 24)	175	10MAY2011	12:03	YES	NO	
			V6 (WEEK 52)	371	22NOV2011	12:30	YES	NO	
			V7 (WEEK 56)	394	15DEC2011	10:30			
	086	21	SCREENING	-24	04OCT2010	11:00	YES	NO	
			V1 (WEEK 0)	1	28OCT2010	14:05	YES	NO	
			V3 (WEEK 12)	83	18JAN2011	11:30	YES	NO	
			V4 (WEEK 24)	167	12APR2011	11:55	YES	NO	
			V5 (WEEK 36)	251	05JUL2011	11:57			
			V6 (WEEK 52)	363	25OCT2011	13:20	YES	NO	
			V7 (WEEK 56)	391	22NOV2011	11:55			
	088	16	SCREENING	-9	30NOV2010	10:15	YES	NO	
			V1 (WEEK 0)	1	09DEC2010	9:20	YES	NO	
			V3 (WEEK 12)	83	01MAR2011	11:00	YES	NO	
			V4 (WEEK 24)	162	19MAY2011	9:45	YES	NO	
			V5 (WEEK 36)	264	29AUG2011	9:50			

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Listing 16.2.8.1.2: Assessment of laboratory values (urine)

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Result for pregnancy test	Specification, if not done
Placebo	082	17	V4 (WEEK 24)	175		
			V6 (WEEK 52)	364		
			V7 (WEEK 56)	407		
	084	17	SCREENING	-9		
			V1 (WEEK 0)	1		
			V3 (WEEK 12)	84		
			V4 (WEEK 24)	175		
			V6 (WEEK 52)	371		
			V7 (WEEK 56)	394		
	086	21	SCREENING	-24		
			V1 (WEEK 0)	1	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V3 (WEEK 12)	83	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V4 (WEEK 24)	167	NOT DONE	POSTMENOPAUSAL
			V5 (WEEK 36)	251	NOT DONE	PATIENT IS POSTMENOPAUSAL
			V6 (WEEK 52)	363	NOT DONE	N/A
			V7 (WEEK 56)	391		
	088	16	SCREENING	-9		
			V1 (WEEK 0)	1	NOT DONE	TOTAL EXTIRPATION
			V3 (WEEK 12)	83	NOT DONE	TOTAL SURGERY 2006
			V4 (WEEK 24)	162		
			V5 (WEEK 36)	264	NOT DONE	CLIMACTERIUM

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
ACI-91	002	1	V3 (WEEK 12)	85	16JUL2009	YES	NO	
			V6 (WEEK 52)	365	21APR2010	YES	NO	
	004	1	V3 (WEEK 12)	92				FLUID SAMPLING REFUSED - COAGULATION TEST NOT NECESSARY
	006	2	V3 (WEEK 12)	85	21MAY2010	YES	NO	
			V6 (WEEK 52)	364	24FEB2011	YES	NO	
	010	1	V3 (WEEK 12)	85	08OCT2009	YES	NO	
	012	1	V6 (WEEK 52)	361	12JUL2011	YES	NO	
	014	4	V1 (WEEK 0)	1	02NOV2009	YES	NO	
			V3 (WEEK 12)	85				NOT DONE
			V6 (WEEK 52)	361	28OCT2010	YES	NO	
	015	4	V1 (WEEK 0)	1	22FEB2010	YES	NO	
			V6 (WEEK 52)	365	21FEB2011	YES	NO	
	017	5	V1 (WEEK 0)	1	05AUG2009	YES	NO	
			V3 (WEEK 12)	85	26OCT2009	YES	NO	
			V6 (WEEK 52)	364	03AUG2010	YES	NO	

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
ACI-91	019	5	V1 (WEEK 0)	1	18NOV2009	YES	NO	
			V3 (WEEK 12)	85	03MAR2010	YES	NO	
			V6 (WEEK 52)	364	07DEC2010	YES	NO	
	023	4	V1 (WEEK 0)	1	20JUL2010	YES	NO	
			V6 (WEEK 52)	364	18JUL2011	YES	NO	
	027	20	V1 (WEEK 0)	1	21OCT2010	YES	NO	
			V6 (WEEK 52)	370	25OCT2011	YES	NO	
	030	8	V1 (WEEK 0)	1	25MAR2010	YES	NO	
			V6 (WEEK 52)	355	14MAR2011	YES	NO	
	032	8	V1 (WEEK 0)	1	18NOV2010	YES	NO	
	033	9	V1 (WEEK 0)	1	04NOV2009	YES	NO	
			V6 (WEEK 52)	372	10NOV2010	YES	NO	
	042	12	V1 (WEEK 0)	1	14JAN2010	YES	NO	
			V3 (WEEK 12)	126	19MAY2010	YES	NO	
			V6 (WEEK 52)	364	12JAN2011	YES	NO	
	043	12	V1 (WEEK 0)	1	18NOV2009	YES	NO	
			V3 (WEEK 12)	85	10FEB2010	YES	NO	

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
ACI-91	043	12	V6 (WEEK 52)	267		NO		
	046	11	V1 (WEEK 0)	1	11JAN2010	YES	NO	
			V3 (WEEK 12)	87		NO		
			V6 (WEEK 52)	367	12JAN2011	YES	NO	
	048	11	V1 (WEEK 0)	1	22NOV2010	YES	NO	
			V6 (WEEK 52)	360	16NOV2011	YES	NO	
	050	21	V1 (WEEK 0)	1	27OCT2010	YES	NO	
			V6 (WEEK 52)	363	24OCT2011	YES	NO	
	052	21	V1 (WEEK 0)	1	28OCT2010	YES	NO	
			V6 (WEEK 52)	362	24OCT2011	YES	NO	
	055	5	V1 (WEEK 0)	1	29MAR2010	YES	NO	
			V6 (WEEK 52)	30		NO		
	066	16	V1 (WEEK 0)	1	09SEP2010	YES	NO	
	067	16	V1 (WEEK 0)	1				NOT DONE
			V6 (WEEK 52)	69				NOT DONE, EARLY TERMINATION
	071	18	V1 (WEEK 0)	1	09NOV2010	YES	NO	

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
ACI-91	071	18	V6 (WEEK 52)	374	15NOV2011	YES	NO	
	080	13	V1 (WEEK 0)	1	19NOV2010	YES	NO	
			V3 (WEEK 12)	84	09FEB2011	YES	NO	
	081	17	V1 (WEEK 0)	1	14OCT2010	YES	NO	
	083	17	V1 (WEEK 0)	1	10NOV2010	YES	NO	
			V6 (WEEK 52)	365	09NOV2011	YES	NO	
	087	16	V6 (WEEK 52)	365	21NOV2011	YES	NO	
	089	5	V1 (WEEK 0)	1	19OCT2010	YES	NO	
			V3 (WEEK 12)	84				NOT DONE
			V6 (WEEK 52)	364	25JUL2011	YES	NO	
	093	17	V1 (WEEK 0)	1	02DEC2010	YES	NO	
			V3 (WEEK 12)	86				OPTIONAL
Placebo	097	12	V1 (WEEK 0)	1	17NOV2010	YES	NO	
			V3 (WEEK 12)	85	09FEB2011	YES	NO	
	001	1	V3 (WEEK 12)	90	07JUL2009	YES	NO	
			V6 (WEEK 52)	365	07APR2010	YES	NO	

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
Placebo	005	2	V1 (WEEK 0)	1	04JUN2009	YES	NO	
			V3 (WEEK 12)	83	25AUG2009	YES	NO	
			V6 (WEEK 52)	364	02JUN2010	YES	NO	
	009	1	V3 (WEEK 12)	94	10DEC2009	YES	NO	
			V6 (WEEK 52)	361	03SEP2010	YES	NO	
	011	1	V3 (WEEK 12)	85	18FEB2010	YES	NO	
			V6 (WEEK 52)	366	25NOV2010	YES	NO	
	013	4	V1 (WEEK 0)	1	16SEP2009	YES	NO	
			V3 (WEEK 12)	85	09DEC2009	YES	NO	
			V6 (WEEK 52)	366	16SEP2010	YES	NO	
	016	4	V1 (WEEK 0)	1	01MAR2010	YES	NO	
			V6 (WEEK 52)	365	28FEB2011	YES	NO	
	018	5	V1 (WEEK 0)	1	18NOV2009	YES	NO	
			V3 (WEEK 12)	86	16FEB2010	YES	NO	
			V6 (WEEK 52)	366	23NOV2010	YES	NO	
	020	5	V1 (WEEK 0)	1	22FEB2010	YES	NO	
	024	4	V1 (WEEK 0)	1	16AUG2010	YES	NO	

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
Placebo	024	4	V6 (WEEK 52)	358	08AUG2011	YES	NO	
	028	20	V1 (WEEK 0)	1	26NOV2010	YES	NO	
			V6 (WEEK 52)	364	24NOV2011	YES	NO	
	029	8	V1 (WEEK 0)	1	29JAN2010	YES	NO	
	031	8	V1 (WEEK 0)	1	20MAY2010	YES	NO	
	034	9	V1 (WEEK 0)	1	18MAR2010	YES	NO	
			V3 (WEEK 12)	83	15JUN2010	YES	NO	
			V6 (WEEK 52)	363	15MAR2011	YES	NO	
	041	12	V1 (WEEK 0)	1	09OCT2009	YES	NO	
			V3 (WEEK 12)	89	05JAN2010	YES	NO	
			V6 (WEEK 52)	363	06OCT2010	YES	NO	
	044	12	V1 (WEEK 0)	1	02DEC2009	YES	NO	
			V3 (WEEK 12)	85	24FEB2010	YES	NO	
			V6 (WEEK 52)	365	01DEC2010	YES	NO	
	045	11	V1 (WEEK 0)	1	21DEC2009	YES	NO	
			V3 (WEEK 12)	85		NO		
			V6 (WEEK 52)	360	15DEC2010	YES	NO	

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
Placebo	047	11	V1 (WEEK 0)	1	02AUG2010	YES	NO	
			V3 (WEEK 12)	80		NO		
			V6 (WEEK 52)	360	27JUL2011	YES	NO	
	049	21	V1 (WEEK 0)	1	27OCT2010	YES	NO	
	051	21	V1 (WEEK 0)	1	28OCT2010	YES	NO	
			V6 (WEEK 52)	363	25OCT2011	YES	NO	
	056	5	V1 (WEEK 0)	1	31MAR2010	YES	NO	
			V3 (WEEK 12)	84		NO		TEST NOT DONE_ NO LUMBAR PUNCTURE PERFORMED
			V6 (WEEK 52)	364	19APR2011	YES	NO	
	058	1	V6 (WEEK 52)	345	06DEC2011	YES	NO	
	059	1	V6 (WEEK 52)	345	21NOV2011	YES	NO	
	068	16	V3 (WEEK 12)	81				NOT DONE, BECAUSE OF OPTIONAL LP, PATIENT DONT GIVE PERMISSION
			V6 (WEEK 52)	372	25NOV2011	YES	NO	
	069	23	V1 (WEEK 0)	1	07DEC2010	YES	NO	
			V6 (WEEK 52)	373	14DEC2011	YES	NO	

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Listing 16.2.8.1.3: Assessment of laboratory values (coagulation)

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of sampling	Result reviewed	Clinic. signif. finding	Specification
Placebo	072	18	V1 (WEEK 0)	1	21DEC2010	YES	NO	
			V6 (WEEK 52)	360	12DEC2011	YES	NO	
	079	13	V1 (WEEK 0)	1	12AUG2010	YES	NO	
			V3 (WEEK 12)	96	09NOV2010	YES	NO	
			V6 (WEEK 52)	320	21JUN2011	YES	NO	
	082	17	V1 (WEEK 0)	1	14OCT2010	YES	NO	
			V6 (WEEK 52)	364	12OCT2011	YES	NO	
	084	17	V1 (WEEK 0)	1	17NOV2010	YES	NO	
			V6 (WEEK 52)	371	23NOV2011	YES	NO	
	086	21	V1 (WEEK 0)	1	28OCT2010	YES	NO	
			V6 (WEEK 52)	363	25OCT2011	YES	NO	
	088	16	V3 (WEEK 12)	83				NOT PERFORMED -> LUMBAR PUNCTURE IS OPTIONAL
			V6 (WEEK 52)	376	12DEC2011	YES	NO	

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	002	1	SCREENING	-7	16APR2009	10:00	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.5	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	60	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 35
							SGPT (ALT)	41	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	69	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	5	mmol/L			< 6.50
							TRIGLYCERIDES	1.29	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
							T3	1.56	nmol/L			1.2 - 3.1
							T4	98	nmol/L			65.8 - 182
							TSH	1	mU/L			0.27 - 4.20

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	002	1	SCREENING	-7	16APR2009	10:00	B12	497	pmol/L			145 - 639
							FOLATE	36.7	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	4.4	U/L			< 5.0
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	23.4	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	40	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	41	U/L	HIGH	NCS	< 35
							ALKALINE	69	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	5.21	mmol/L			< 6.50
							TRIGLYCERIDES	1.07	mmol/L			0.57 - 2.28
							URIC ACID	238	µmol/L			< 357

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	002	1	V3 (WEEK 12)	85	16JUL2009	8:30	SODIUM	147	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	18.4	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	59	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 35
							SGPT (ALT)	35	U/L	HIGH	NCS	< 35
							ALKALINE	79	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	4.71	mmol/L			< 6.50
			V4 (WEEK 24)	169	08OCT2009	10:30	TRIGLYCERIDES	0.88	mmol/L			0.57 - 2.28
							URIC ACID	220	µmol/L			< 357
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	5.3	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	002	1	V4 (WEEK 24)	169	08OCT2009	10:30	BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	69	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	40	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	40	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	75	U/L			35 - 105
							GAMMA-GT	22	U/L			< 40
							CHOLESTEROL	4.71	mmol/L			< 6.50
							TRIGLYCERIDES	1.43	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	258	05JAN2010	9:25	URIC ACID	268	µmol/L			< 357
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	5.5	mmol/L	HIGH	NCS	3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	70	µmol/L			< 97

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	002	1	V5 (WEEK 36)	258	05JAN2010	9:25	CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.11	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	45	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	61	U/L	HIGH	NCS	< 35
							ALKALINE	77	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	5.44	mmol/L			< 6.50
							TRIGLYCERIDES	1.21	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
			V6 (WEEK 52)	365	22APR2010	10:10	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	76	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.23	mmol/L			2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	002	1	V6 (WEEK 52)	365	22APR2010	10:10	TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	39	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	40	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	75	U/L			35 - 105
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	5.05	mmol/L			< 6.50
							TRIGLYCERIDES	0.96	mmol/L			0.57 - 2.28
							URIC ACID	291	µmol/L			< 357
			V7 (WEEK 56)	393	20MAY2010	9:15	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	5.5	mmol/L	HIGH	NCS	3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25.8	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	78	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	3.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0
							ALBUMIN	42.9	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	002	1	V7 (WEEK 56)	393	20MAY2010	9:15	SGOT (AST)	31	U/L			10 - 35
							SGPT (ALT)	30	U/L			< 35
							ALKALINE PHOSPHATASE	65	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	5.08	mmol/L			< 6.50
							TRIGLYCERIDES	1.43	mmol/L			0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
	004	1	SCREENING	-29	17JUN2009	11:40	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	24.9	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	18	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	004	1	SCREENING	-29	17JUN2009	11:40	ALKALINE PHOSPHATASE	54	U/L			40 - 130
							GAMMA-GT	19	U/L			< 60
							CHOLESTEROL	7.3	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.6	mmol/L			0.57 - 2.28
							URIC ACID	387	µmol/L			< 416
							T3	1.06	nmol/L	LOW	NCS	1.2 - 3.1
							T4	73.5	nmol/L			65.8 - 182
							TSH	1.5	mU/L			0.27 - 4.20
							B12	260	pmol/L			145 - 639
							FOLATE	16.1	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	16JUL2009	10:00	SODIUM	147	mmol/L			135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	19.6	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	73	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.61	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	004	1	V1 (WEEK 0)	1	16JUL2009	10:00	SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	59	U/L			40 - 130
							GAMMA-GT	16	U/L			< 60
							CHOLESTEROL	6.27	mmol/L			< 6.50
							TRIGLYCERIDES	0.95	mmol/L			0.57 - 2.28
							URIC ACID	399	µmol/L			< 416
			V3 (WEEK 12)	92	15OCT2009	14:50	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	28.4	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	78	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.89	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	16	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	004	1	V3 (WEEK 12)	92	15OCT2009	14:50	ALKALINE PHOSPHATASE	74	U/L			40 - 130
							GAMMA-GT	15	U/L			< 60
							CHOLESTEROL	6.79	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.53	mmol/L			0.57 - 2.28
							URIC ACID	387	µmol/L			< 416
	006	2	SCREENING	-32	25JAN2010	8:45	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	28.9	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.7	mmol/L	LOW	NCS	0.8 - 1.6
							GLUCOSE	7.17	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	46.8	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	31	U/L			< 50
							ALKALINE PHOSPHATASE	68	U/L			40 - 130

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	006	2	SCREENING	-32	25JAN2010	8:45	GAMMA-GT	39	U/L			< 60
							CHOLESTEROL	6.76	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.73	mmol/L			0.57 - 2.28
							URIC ACID	416	µmol/L	HIGH	NCS	< 416
							T3	1.63	nmol/L			1.2 - 3.1
							T4	89	nmol/L			65.8 - 182
							TSH	0.64	mU/L			0.27 - 4.20
							B12	229	pmol/L			145 - 639
							FOLATE	45.3	nmol/L	HIGH	NCS	10.4 - 42.4
			V1 (WEEK 0)	1	26FEB2010	9:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	27.2	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	88	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	6.62	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	23.9	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 50
							SGPT (ALT)	34	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	006	2	V1 (WEEK 0)	1	26FEB2010	9:00	ALKALINE PHOSPHATASE	58	U/L			40 - 130
							GAMMA-GT	41	U/L			< 60
							CHOLESTEROL	7.43	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.15	mmol/L			0.57 - 2.28
							URIC ACID	404	µmol/L			< 416
			V3 (WEEK 12)	85	21MAY2010	9:15	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	21.8	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	95	µmol/L			< 106
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	6.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	80	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	31	U/L			< 50
							ALKALINE PHOSPHATASE	61	U/L			40 - 130
							GAMMA-GT	42	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	006	2	V3 (WEEK 12)	85	21MAY2010	9:15	CHOLESTEROL	7.9	mmol/L	HIGH	NCS	< 6.50
			V4 (WEEK 24)	169	13AUG2010	9:00	TRIGLYCERIDES	2.33	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	428	µmol/L	HIGH	NCS	< 416
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	93	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	7.01	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	18.8	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	34	U/L			< 50
							ALKALINE PHOSPHATASE	56	U/L			40 - 130
							GAMMA-GT	38	U/L			< 60
							CHOLESTEROL	6.73	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.29	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	434	µmol/L	HIGH	NCS	< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	006	2	V5 (WEEK 36)	252	04NOV2010	8:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	93	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	29	mmol/L			22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	85.7	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	7.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	49.9	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	38	U/L			< 50
							ALKALINE PHOSPHATASE	57	U/L			40 - 130
							GAMMA-GT	37	U/L			< 60
							CHOLESTEROL	6.97	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.21	mmol/L			0.57 - 2.28
							URIC ACID	393	µmol/L			< 416
			V6 (WEEK 52)	364	24FEB2011	8:20	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	006	2	V6 (WEEK 52)	364	24FEB2011	8:20	BICARBONATE	28.2	mmol/L			22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	85.7	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	45	U/L			< 50
							ALKALINE	62	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	38	U/L			< 60
							CHOLESTEROL	6.89	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.81	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	390	22MAR2011	8:30	URIC ACID	422	µmol/L	HIGH	NCS	< 416
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	26.4	mmol/L			22.0 - 29.0
							UREA	3.51	mmol/L			< 8.40
							CREATININE	85.7	µmol/L			59.2 - 103.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	006	2	V7 (WEEK 56)	390	22MAR2011	8:30	CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	7.45	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 50
							SGPT (ALT)	42	U/L			< 50
							ALKALINE	55	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	33	U/L			< 60
							CHOLESTEROL	6.97	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.58	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	416	µmol/L	HIGH	NCS	< 416
	010	1	SCREENING	-26	25JUN2009	9:45	SODIUM	148	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	20	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	74	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	010	1	SCREENING	-26	25JUN2009	9:45	GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	25	U/L			< 50
							ALKALINE PHOSPHATASE	89	U/L			40 - 130
							GAMMA-GT	27	U/L			< 60
							CHOLESTEROL	6.09	mmol/L			< 6.50
							TRIGLYCERIDES	2.31	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	256	µmol/L			< 416
							T3	0.99	nmol/L	LOW	NCS	1.2 - 3.1
							T4	51.6	nmol/L	LOW	NCS	65.8 - 182
							TSH	0.47	mU/L			0.27 - 4.20
							B12	224	pmol/L			145 - 639
			V1 (WEEK 0)	1	21JUL2009	11:00	FOLATE	35.3	nmol/L			10.4 - 42.4
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	23.4	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 106

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	010	1	V1 (WEEK 0)	1	21JUL2009	11:00	CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	15	U/L			< 50
							ALKALINE PHOSPHATASE	91	U/L			40 - 130
							GAMMA-GT	23	U/L			< 60
							CHOLESTEROL	6.19	mmol/L			< 6.50
							TRIGLYCERIDES	1.81	mmol/L			0.57 - 2.28
							URIC ACID	238	µmol/L			< 416
			V3 (WEEK 12)	85	13OCT2009	10:45	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	70	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.5	mmol/L			2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	010	1	V3 (WEEK 12)	85	13OCT2009	10:45	TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 50
							SGPT (ALT)	21	U/L			< 50
							ALKALINE PHOSPHATASE	80	U/L			40 - 130
							GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	5.67	mmol/L			< 6.50
							TRIGLYCERIDES	1.76	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 416
	012	1	SCREENING	-32	17JUN2010	12:20	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	30	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	7.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	012	1	SCREENING	-32	17JUN2010	12:20	ALBUMIN	41.2	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 50
							SGPT (ALT)	14	U/L			< 50
							ALKALINE PHOSPHATASE	62	U/L			40 - 130
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	4.69	mmol/L			< 6.50
							TRIGLYCERIDES	0.67	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 416
							T3	1.2	nmol/L	LOW	NCS	1.2 - 3.1
							T4	86.4	nmol/L			65.8 - 182
							TSH	0.35	mU/L			0.27 - 4.20
							B12	437	pmol/L			145 - 639
							FOLATE	45.3	nmol/L	HIGH	NCS	10.4 - 42.4
			V1 (WEEK 0)	1	19JUL2010	10:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	29.8	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	68	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	9.23	mmol/L	HIGH	NCS	2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	012	1	V1 (WEEK 0)	1	19JUL2010	10:00	TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L		61.0 - 81.0	
							ALBUMIN	43	g/L		35.0 - 55.0	
							SGOT (AST)	22	U/L		10 - 50	
							SGPT (ALT)	15	U/L		< 50	
							ALKALINE PHOSPHATASE	66	U/L		40 - 130	
							GAMMA-GT	18	U/L		< 60	
							CHOLESTEROL	5.21	mmol/L		< 6.50	
							TRIGLYCERIDES	0.72	mmol/L		0.57 - 2.28	
			V3 (WEEK 12)	88	14OCT2010	9:15	URIC ACID	250	µmol/L		< 416	
							SODIUM	145	mmol/L		135 - 150	
							POTASSIUM	4.9	mmol/L		3.6 - 5.4	
							CHLORIDE	102	mmol/L		95 - 105	
							BICARBONATE	23.2	mmol/L		22.0 - 29.0	
							UREA	5.85	mmol/L		< 8.40	
							CREATININE	74.3	µmol/L		59.2 - 103.4	
							CALCIUM	2.3	mmol/L		2.1 - 2.7	
							PHOSPHATE	1	mmol/L		0.8 - 1.6	
							GLUCOSE	8.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L		< 17.0	
							TOTAL PROTEIN	72	g/L		61.0 - 81.0	
							ALBUMIN	44	g/L		NCS	35.0 - 55.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	012	1	V3 (WEEK 12)	88	14OCT2010	9:15	SGOT (AST)	73	U/L	HIGH	CS	10 - 50
							SGPT (ALT)	150	U/L	HIGH	CS	< 50
							ALKALINE PHOSPHATASE	64	U/L			40 - 130
							GAMMA-GT	29	U/L			< 60
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	0.48	mmol/L	LOW	NCS	0.57 - 2.28
							URIC ACID	262	µmol/L			< 416
			V5 (WEEK 36)	257	01APR2011	9:30	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	5.2	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	29.2	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	82.2	µmol/L			59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	7.9	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	17	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	012	1	V5 (WEEK 36)	257	01APR2011	9:30	ALKALINE PHOSPHATASE	59	U/L			40 - 130
							GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	4.79	mmol/L			< 6.50
			V6 (WEEK 52)	361	14JUL2011	10:25	TRIGLYCERIDES	0.5	mmol/L	LOW	NCS	0.57 - 2.28
							URIC ACID	339	µmol/L			< 416
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	28.9	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	70.7	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	7.45	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	57	U/L			40 - 130
							GAMMA-GT	23	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	012	1	V6 (WEEK 52)	361	14JUL2011	10:25	CHOLESTEROL	5.15	mmol/L			< 6.50
							TRIGLYCERIDES	0.66	mmol/L			0.57 - 2.28
							URIC ACID	286	µmol/L			< 416
			V7 (WEEK 56)	396	18AUG2011	12:20	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	6.85	mmol/L			< 8.40
							CREATININE	70.7	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	7.01	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	43	U/L			40 - 130
							GAMMA-GT	30	U/L			< 60
							CHOLESTEROL	5.44	mmol/L			< 6.50
							TRIGLYCERIDES	0.73	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	014	4	SCREENING	-26	07OCT2009	11:30	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	5.3	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	23.4	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	75	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.5	mmol/L			0.8 - 1.6
							GLUCOSE	4.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50
							ALKALINE PHOSPHATASE	24	U/L	LOW	NCS	40 - 130
							GAMMA-GT	31	U/L			< 60
							CHOLESTEROL	6.03	mmol/L			< 6.50
							TRIGLYCERIDES	2.37	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	327	µmol/L			< 416
							T3	1.72	nmol/L			1.2 - 3.1
							T4	85.1	nmol/L			65.8 - 182
							TSH	0.89	mU/L			0.27 - 4.20

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	014	4	SCREENING	-26	07OCT2009	11:30	B12	215	pmol/L			145 - 639
							FOLATE	18.8	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	02NOV2009	9:30	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	27.3	mmol/L			22.0 - 29.0
							UREA	7.01	mmol/L			< 8.40
							CREATININE	81	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	22	U/L	LOW	NCS	40 - 130
							GAMMA-GT	30	U/L			< 60
							CHOLESTEROL	6.01	mmol/L			< 6.50
							TRIGLYCERIDES	1.69	mmol/L			0.57 - 2.28
							URIC ACID	363	µmol/L			< 416
			V3 (WEEK 12)	85	25JAN2010	10:00	SODIUM	141	mmol/L			135 - 150

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	014	4	V3 (WEEK 12)	85	25JAN2010	10:00	POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	27.4	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	69	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	42.8	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	26	U/L			< 50
							ALKALINE PHOSPHATASE	20	U/L	LOW	NCS	40 - 130
							GAMMA-GT	27	U/L			< 60
							CHOLESTEROL	6.29	mmol/L			< 6.50
							TRIGLYCERIDES	2.6	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	393	µmol/L			< 416
			V4 (WEEK 24)	172	22APR2010	10:15	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	23.5	mmol/L			22.0 - 29.0

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Listing 16.2.8.2: Biochemistry

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	014	4	V4 (WEEK 24)	172	22APR2010	10:15	UREA	7.01	mmol/L			< 8.40
							CREATININE	76	µmol/L			< 106
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	4.78	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	35	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50
							ALKALINE PHOSPHATASE	23	U/L	LOW	NCS	40 - 130
							GAMMA-GT	28	U/L			< 60
							CHOLESTEROL	4.9	mmol/L			< 6.50
							TRIGLYCERIDES	1.35	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	256	15JUL2010	10:30	URIC ACID	339	µmol/L			< 416
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	25.5	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	88	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	014	4	V5 (WEEK 36)	256	15JUL2010	10:30	PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	6.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 50
							SGPT (ALT)	18	U/L			< 50
							ALKALINE	20	U/L	LOW	NCS	40 - 130
							PHOSPHATASE					
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	4.79	mmol/L			< 6.50
							TRIGLYCERIDES	1.31	mmol/L			0.57 - 2.28
							URIC ACID	381	µmol/L			< 416
			V6 (WEEK 52)	361	28OCT2010	11:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26.8	mmol/L			22.0 - 29.0
							UREA	7.35	mmol/L			< 8.40
							CREATININE	77.8	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	014	4	V6 (WEEK 52)	361	28OCT2010	11:00	TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	42.6	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	23	U/L			< 50
							ALKALINE PHOSPHATASE	23	U/L	LOW	NCS	40 - 130
							GAMMA-GT	29	U/L			< 60
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	1	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 416
			V7 (WEEK 56)	396	02DEC2010	11:30	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.1	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	77.8	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	014	4	V7 (WEEK 56)	396	02DEC2010	11:30	SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	22	U/L	LOW	NCS	40 - 130
							GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	4.71	mmol/L			< 6.50
							TRIGLYCERIDES	1.47	mmol/L			0.57 - 2.28
							URIC ACID	339	µmol/L			< 416
	015	4	SCREENING	-32	21JAN2010	10:30	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	65	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	79	g/L			61.0 - 81.0
							ALBUMIN	49.1	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 35
							SGPT (ALT)	27	U/L			< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	015	4	SCREENING	-32	21JAN2010	10:30	ALKALINE	54	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	5.36	mmol/L			< 6.50
							TRIGLYCERIDES	1.89	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
							T3	1.65	nmol/L			1.2 - 3.1
							T4	103.2	nmol/L			65.8 - 182
							TSH	1.76	mU/L			0.27 - 4.20
							B12	349	pmol/L			145 - 639
							FOLATE	19	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	2.1	U/L			< 5.0
			V1 (WEEK 0)	1	22FEB2010	9:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	23.5	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	87	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	015	4	V1 (WEEK 0)	1	22FEB2010	9:00	ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	24	U/L			< 35
							ALKALINE PHOSPHATASE	57	U/L			35 - 105
							GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	5.49	mmol/L			< 6.50
							TRIGLYCERIDES	1.77	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	85	17MAY2010	10:00	URIC ACID	345	µmol/L			< 357
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	20.3	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	85	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.62	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	37	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	23	U/L			< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	015	4	V3 (WEEK 12)	85	17MAY2010	10:00	ALKALINE PHOSPHATASE	65	U/L			35 - 105
			V4 (WEEK 24)	162	02AUG2010	9:30	GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	6.24	mmol/L			< 6.50
							TRIGLYCERIDES	2.84	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	357	µmol/L	HIGH	NCS	< 357
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	20.5	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	78	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	65	U/L			35 - 105
							GAMMA-GT	27	U/L			< 40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	015	4	V4 (WEEK 24)	162	02AUG2010	9:30	CHOLESTEROL	6.09	mmol/L			< 6.50
							TRIGLYCERIDES	1.8	mmol/L			0.57 - 2.28
							URIC ACID	351	µmol/L			< 357
			V5 (WEEK 36)	248	27OCT2010	9:45	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	86.6	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	24	U/L			< 35
							ALKALINE	58	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	25	U/L			< 40
							CHOLESTEROL	5.62	mmol/L			< 6.50
							TRIGLYCERIDES	1.07	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L	HIGH	NCS	< 357

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	015	4	V6 (WEEK 52)	365	21FEB2011	10:30	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	26	mmol/L			22.0 - 29.0
							UREA	3.34	mmol/L			< 8.40
							CREATININE	82.2	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	29	U/L			< 35
							ALKALINE PHOSPHATASE	68	U/L			35 - 105
							GAMMA-GT	31	U/L			< 40
							CHOLESTEROL	5.8	mmol/L			< 6.50
							TRIGLYCERIDES	2.12	mmol/L			0.57 - 2.28
							URIC ACID	339	µmol/L			< 357
			V7 (WEEK 56)	394	22MAR2011	10:15	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	015	4	V7 (WEEK 56)	394	22MAR2011	10:15	BICARBONATE	21.6	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	90.2	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.6	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	24	U/L			< 35
							ALKALINE	61	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	5.67	mmol/L			< 6.50
							TRIGLYCERIDES	1.62	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
	017	5	SCREENING	-22	14JUL2009	10:30	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	19.6	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	7.01	mmol/L			< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	017	5	SCREENING	-22	14JUL2009	10:30	CREATININE	95	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	45.4	g/L			35.0 - 55.0
							SGOT (AST)	39	U/L			10 - 50
							SGPT (ALT)	24	U/L			< 50
							ALKALINE PHOSPHATASE	88	U/L			40 - 130
							GAMMA-GT	46	U/L			< 60
							CHOLESTEROL	5.46	mmol/L			< 6.50
							TRIGLYCERIDES	1.77	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L			< 416
							T3	1.22	nmol/L	LOW	NCS	1.2 - 3.1
							T4	77.4	nmol/L			65.8 - 182
							TSH	0.64	mU/L			0.27 - 4.20
							B12	295	pmol/L			145 - 639
							FOLATE	29	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	05AUG2009	9:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	017	5	V1 (WEEK 0)	1	05AUG2009	9:00	BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	8.35	mmol/L			< 8.40
							CREATININE	105	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.89	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	37	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50
							ALKALINE PHOSPHATASE	96	U/L			40 - 130
							GAMMA-GT	39	U/L			< 60
							CHOLESTEROL	4.27	mmol/L			< 6.50
							TRIGLYCERIDES	0.78	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	85	28OCT2009	8:45	URIC ACID	446	µmol/L	HIGH	NCS	< 416
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	96	µmol/L			< 106

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	017	5	V3 (WEEK 12)	85	28OCT2009	8:45	CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	46.2	g/L			35.0 - 55.0
							SGOT (AST)	45	U/L			10 - 50
							SGPT (ALT)	37	U/L			< 50
							ALKALINE	90	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	37	U/L			< 60
							CHOLESTEROL	4.97	mmol/L			< 6.50
							TRIGLYCERIDES	0.72	mmol/L			0.57 - 2.28
			V4 (WEEK 24)	169	20JAN2010	9:00	URIC ACID	333	µmol/L			< 416
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	25.7	mmol/L			22.0 - 29.0
							UREA	7.85	mmol/L			< 8.40
							CREATININE	85	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
GLUCOSE	5.12	mmol/L			2.78 - 5.55							

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	017	5	V4 (WEEK 24)	169	20JAN2010	9:00	TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L		61.0 - 81.0	
							ALBUMIN	45	g/L		35.0 - 55.0	
							SGOT (AST)	33	U/L		10 - 50	
							SGPT (ALT)	34	U/L		< 50	
							ALKALINE PHOSPHATASE	80	U/L		40 - 130	
							GAMMA-GT	38	U/L		< 60	
							CHOLESTEROL	5.18	mmol/L		< 6.50	
							TRIGLYCERIDES	0.66	mmol/L		0.57 - 2.28	
							URIC ACID	333	µmol/L		< 416	
			V5 (WEEK 36)	252	13APR2010	10:45	SODIUM	137	mmol/L		135 - 150	
							POTASSIUM	4.1	mmol/L		3.6 - 5.4	
							CHLORIDE	97	mmol/L		95 - 105	
							BICARBONATE	21.1	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.51	mmol/L		< 8.40	
							CREATININE	103	µmol/L		< 106	
							CALCIUM	2.4	mmol/L		2.1 - 2.7	
							PHOSPHATE	0.9	mmol/L		0.8 - 1.6	
							GLUCOSE	5.45	mmol/L		2.78 - 5.55	
							TOTAL BILIRUBIN	6.8	µmol/L		< 17.0	
							TOTAL PROTEIN	73	g/L		61.0 - 81.0	
							ALBUMIN	46.8	g/L		35.0 - 55.0	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	017	5	V5 (WEEK 36)	252	13APR2010	10:45	SGOT (AST)	40	U/L			10 - 50
							SGPT (ALT)	45	U/L			< 50
							ALKALINE PHOSPHATASE	86	U/L			40 - 130
							GAMMA-GT	34	U/L			< 60
							CHOLESTEROL	5.23	mmol/L			< 6.50
							TRIGLYCERIDES	0.95	mmol/L			0.57 - 2.28
							URIC ACID	351	µmol/L			< 416
			V6 (WEEK 52)	364	03AUG2010	9:00	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	23.7	mmol/L			22.0 - 29.0
							UREA	7.52	mmol/L			< 8.40
							CREATININE	103	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	25	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	017	5	V6 (WEEK 52)	364	03AUG2010	9:00	ALKALINE PHOSPHATASE	71	U/L			40 - 130
							GAMMA-GT	40	U/L			< 60
							CHOLESTEROL	5.98	mmol/L			< 6.50
							TRIGLYCERIDES	1.48	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	392	31AUG2010	9:00	URIC ACID	399	µmol/L			< 416
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0
							UREA	8.52	mmol/L	HIGH	NCS	< 8.40
							CREATININE	115	µmol/L	HIGH	NCS	< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	26	U/L			< 50
							ALKALINE PHOSPHATASE	82	U/L			40 - 130
							GAMMA-GT	42	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	017	5	V7 (WEEK 56)	392	31AUG2010	9:00	CHOLESTEROL	6.09	mmol/L			< 6.50
							TRIGLYCERIDES	0.99	mmol/L			0.57 - 2.28
							URIC ACID	363	µmol/L			< 416
	019	5	SCREENING	-21	18NOV2009	13:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.3	mmol/L			22.0 - 29.0
							UREA	9.02	mmol/L	HIGH	NCS	< 8.40
							CREATININE	94	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	6.45	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 50
							SGPT (ALT)	21	U/L			< 50
							ALKALINE	48	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	31	U/L			< 60
							CHOLESTEROL	3.65	mmol/L			< 6.50
							TRIGLYCERIDES	2.36	mmol/L	HIGH	NCS	0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	019	5	SCREENING	-21	18NOV2009	13:00	URIC ACID	387	µmol/L			< 416
							T3	1.93	nmol/L			1.2 - 3.1
							T4	91.6	nmol/L			65.8 - 182
							TSH	0.2	mU/L	LOW	NCS	0.27 - 4.20
							B12	186	pmol/L			145 - 639
							FOLATE	14.9	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	09DEC2009	9:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	22	mmol/L			22.0 - 29.0
							UREA	11.36	mmol/L	HIGH	NCS	< 8.40
							CREATININE	88	µmol/L			< 106
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	7.17	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50
							ALKALINE	47	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	30	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	019	5	V1 (WEEK 0)	1	09DEC2009	9:00	CHOLESTEROL	4.64	mmol/L			< 6.50
							TRIGLYCERIDES	1.9	mmol/L			0.57 - 2.28
							URIC ACID	404	µmol/L			< 416
			V3 (WEEK 12)	85	03MAR2010	9:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	23.2	mmol/L			22.0 - 29.0
							UREA	8.52	mmol/L	HIGH	NCS	< 8.40
							CREATININE	99	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	6.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	44.8	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE PHOSPHATASE	35	U/L	LOW	NCS	40 - 130
							GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	2.26	mmol/L			0.57 - 2.28
							URIC ACID	387	µmol/L			< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	019	5	V4 (WEEK 24)	168	25MAY2010	9:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	23.5	mmol/L			22.0 - 29.0
							UREA	9.69	mmol/L	HIGH	NCS	< 8.40
							CREATININE	112	µmol/L	HIGH	NCS	< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE PHOSPHATASE	39	U/L	LOW	NCS	40 - 130
							GAMMA-GT	25	U/L			< 60
							CHOLESTEROL	4.82	mmol/L			< 6.50
							TRIGLYCERIDES	2.06	mmol/L			0.57 - 2.28
							URIC ACID	458	µmol/L	HIGH	NCS	< 416
			V5 (WEEK 36)	259	24AUG2010	12:00	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	019	5	V5 (WEEK 36)	259	24AUG2010	12:00	BICARBONATE	23.1	mmol/L			22.0 - 29.0
							UREA	9.02	mmol/L	HIGH	NCS	< 8.40
							CREATININE	112	µmol/L	HIGH	NCS	< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	42.5	g/L			35.0 - 55.0
							SGOT (AST)	35	U/L			10 - 50
							SGPT (ALT)	25	U/L			< 50
							ALKALINE PHOSPHATASE	40	U/L			40 - 130
							GAMMA-GT	22	U/L			< 60
							CHOLESTEROL	4.25	mmol/L			< 6.50
							TRIGLYCERIDES	1.93	mmol/L			0.57 - 2.28
			V6 (WEEK 52)	364	07DEC2010	13:30	URIC ACID	458	µmol/L	HIGH	NCS	< 416
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.6	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	8.52	mmol/L	HIGH	NCS	< 8.40
							CREATININE	91.9	µmol/L			59.2 - 103.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	019	5	V6 (WEEK 52)	364	07DEC2010	13:30	CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	6.89	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 50
							SGPT (ALT)	23	U/L			< 50
							ALKALINE PHOSPHATASE	38	U/L	LOW	NCS	40 - 130
							GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	5.05	mmol/L			< 6.50
							TRIGLYCERIDES	1.87	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	399	11JAN2011	9:10	URIC ACID	428	µmol/L	HIGH	NCS	< 416
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.7	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	23	mmol/L			22.0 - 29.0
							UREA	9.85	mmol/L	HIGH	NCS	< 8.40
							CREATININE	103.4	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.7	mmol/L	LOW	NCS	0.8 - 1.6
							GLUCOSE	6.95	mmol/L	HIGH	NCS	2.78 - 5.55

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	019	5	V7 (WEEK 56)	399	11JAN2011	9:10	TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	31	U/L			10 - 50
							SGPT (ALT)	27	U/L			< 50
							ALKALINE PHOSPHATASE	39	U/L	LOW	NCS	40 - 130
							GAMMA-GT	28	U/L			< 60
							CHOLESTEROL	4.95	mmol/L			< 6.50
							TRIGLYCERIDES	1.71	mmol/L			0.57 - 2.28
							URIC ACID	440	µmol/L	HIGH	NCS	< 416
	023	4	SCREENING	-19	01JUL2010	11:00	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	26.2	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	92	µmol/L			< 106
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	3.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	023	4	SCREENING	-19	01JUL2010	11:00	ALBUMIN	43.4	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE PHOSPHATASE	79	U/L			40 - 130
							GAMMA-GT	19	U/L			< 60
							CHOLESTEROL	4.71	mmol/L			< 6.50
							TRIGLYCERIDES	1.29	mmol/L			0.57 - 2.28
							URIC ACID	232	µmol/L			< 416
							T3	1.36	nmol/L			1.2 - 3.1
							T4	71	nmol/L			65.8 - 182
							TSH	1.75	mU/L			0.27 - 4.20
							B12	229	pmol/L			145 - 639
							FOLATE	13.4	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	20JUL2010	10:00	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	3.51	mmol/L			< 8.40
							CREATININE	91	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.06	mmol/L	HIGH	NCS	2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	023	4	V1 (WEEK 0)	1	20JUL2010	10:00	TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L		61.0 - 81.0	
							ALBUMIN	44	g/L		35.0 - 55.0	
							SGOT (AST)	24	U/L		10 - 50	
							SGPT (ALT)	19	U/L		< 50	
							ALKALINE PHOSPHATASE	90	U/L		40 - 130	
							GAMMA-GT	17	U/L		< 60	
							CHOLESTEROL	4.53	mmol/L		< 6.50	
							TRIGLYCERIDES	2.46	mmol/L	HIGH	NCS	0.57 - 2.28
			V3 (WEEK 12)	86	13OCT2010	9:30	URIC ACID	274	µmol/L			< 416
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.8	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	96.4	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	6.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	023	4	V3 (WEEK 12)	86	13OCT2010	9:30	SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	24	U/L			< 50
							ALKALINE PHOSPHATASE	80	U/L			40 - 130
							GAMMA-GT	19	U/L			< 60
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	1.62	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 416
			V4 (WEEK 24)	177	12JAN2011	10:30	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25.9	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	98.1	µmol/L			59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	41.5	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	25	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	023	4	V4 (WEEK 24)	177	12JAN2011	10:30	ALKALINE PHOSPHATASE	80	U/L			40 - 130
							GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	4.74	mmol/L			< 6.50
							TRIGLYCERIDES	2.01	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 416
			V5 (WEEK 36)	245	21MAR2011	9:45	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	22.9	mmol/L			22.0 - 29.0
							UREA	3.51	mmol/L			< 8.40
							CREATININE	95.5	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	6.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 50
							SGPT (ALT)	21	U/L			< 50
							ALKALINE PHOSPHATASE	80	U/L			40 - 130
							GAMMA-GT	24	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	023	4	V5 (WEEK 36)	245	21MAR2011	9:45	CHOLESTEROL	4.97	mmol/L			< 6.50
							TRIGLYCERIDES	2.22	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 416
			V6 (WEEK 52)	364	18JUL2011	10:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	97.2	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50
							ALKALINE PHOSPHATASE	80	U/L			40 - 130
							GAMMA-GT	28	U/L			< 60
							CHOLESTEROL	4.74	mmol/L			< 6.50
							TRIGLYCERIDES	1.78	mmol/L			0.57 - 2.28
							URIC ACID	309	µmol/L			< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	023	4	V7 (WEEK 56)	388	11AUG2011	11:15	SODIUM	142	mmol/L	HIGH		135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L			95 - 105
							BICARBONATE	27.9	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	90.2	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	29	U/L			< 50
							ALKALINE PHOSPHATASE	79	U/L			40 - 130
							GAMMA-GT	27	U/L			< 60
							CHOLESTEROL	5.13	mmol/L			< 6.50
							TRIGLYCERIDES	1.76	mmol/L			0.57 - 2.28
							URIC ACID	268	µmol/L			< 416
	027	20	SCREENING	-21	30SEP2010	10:35	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	027	20	SCREENING	-21	30SEP2010	10:35	CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	22	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	77.8	µmol/L			58.3 - 96.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	35	U/L			10 - 35
							SGPT (ALT)	28	U/L			< 35
							ALKALINE	90	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	38	U/L			< 40
							CHOLESTEROL	4.71	mmol/L			< 6.50
							TRIGLYCERIDES	2.84	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	440	µmol/L	HIGH	NCS	< 357
							T3	1.54	nmol/L			1.2 - 3.1
							T4	98	nmol/L			65.8 - 182
							TSH	4.16	mU/L			0.27 - 4.20
							B12	384	pmol/L			145 - 639
							FOLATE	17.2	nmol/L			10.4 - 42.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	027	20	SCREENING V1 (WEEK 0)	-21 1	30SEP2010	10:35	BETA-HCG SERUM	1	U/L			< 5.0
					21OCT2010	9:15	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	64.5	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	37	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	93	U/L			35 - 105
							GAMMA-GT	40	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.08	mmol/L			< 6.50
							TRIGLYCERIDES	3.15	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	470	µmol/L	HIGH	NCS	< 357
			V3 (WEEK 12)	92	20JAN2011	10:55	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	027	20	V3 (WEEK 12)	92	20JAN2011	10:55	CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26.6	mmol/L			22.0 - 29.0
							UREA	3.17	mmol/L			< 8.40
							CREATININE	65.4	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	40	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	31	U/L			< 35
							ALKALINE PHOSPHATASE	80	U/L			35 - 105
			V4 (WEEK 24)	174	12APR2011	10:30	GAMMA-GT	48	U/L	HIGH	NCS	< 40
							CHOLESTEROL	4.64	mmol/L			< 6.50
							TRIGLYCERIDES	1.55	mmol/L			0.57 - 2.28
							URIC ACID	416	µmol/L	HIGH	NCS	< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	29.2	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	027	20	V4 (WEEK 24)	174	12APR2011	10:30	CREATININE	70.7	µmol/L			45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	112	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	62	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.23	mmol/L			< 6.50
							TRIGLYCERIDES	3.92	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	440	µmol/L	HIGH	NCS	< 357
			V5 (WEEK 36)	259	06JUL2011	10:55	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	27.2	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	62.8	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	027	20	V5 (WEEK 36)	259	06JUL2011	10:55	GLUCOSE	5.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	36	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	83	U/L			35 - 105
							GAMMA-GT	54	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.26	mmol/L			< 6.50
							TRIGLYCERIDES	1.24	mmol/L			0.57 - 2.28
							URIC ACID	416	µmol/L	HIGH	NCS	< 357
			V6 (WEEK 52)	370	25OCT2011	8:19	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	28.4	mmol/L			22.0 - 29.0
							UREA	2.67	mmol/L			< 8.40
							CREATININE	69.8	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	027	20	V6 (WEEK 52)	370	25OCT2011	8:19	ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	70	U/L			35 - 105
							GAMMA-GT	35	U/L			< 40
							CHOLESTEROL	5.31	mmol/L			< 6.50
							TRIGLYCERIDES	1.71	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	407	01DEC2011	10:10	URIC ACID	434	µmol/L	HIGH	NCS	< 357
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.6	mmol/L			22.0 - 29.0
							UREA	2.34	mmol/L			< 8.40
							CREATININE	62.8	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	027	20	V7 (WEEK 56)	407	01DEC2011	10:10	ALKALINE PHOSPHATASE	87	U/L			35 - 105
							GAMMA-GT	40	U/L	HIGH	NCS	< 40
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	2.47	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	404	µmol/L	HIGH	NCS	< 357
	030	8	SCREENING	-7	18MAR2010	10:30	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	23.6	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	48.9	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE PHOSPHATASE	50	U/L			35 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	030	8	SCREENING	-7	18MAR2010	10:30	GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	5.88	mmol/L			< 6.50
							TRIGLYCERIDES	1.89	mmol/L			0.57 - 2.28
							URIC ACID	315	µmol/L			< 357
							T3	1.16	nmol/L	LOW	NCS	1.2 - 3.1
							T4	109.7	nmol/L			65.8 - 182
							TSH	0.12	mU/L	LOW	NCS	0.27 - 4.20
							B12	202	pmol/L			145 - 639
							FOLATE	14.5	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	5.5	U/L	HIGH	NCS	< 5.0
			V1 (WEEK 0)	1	25MAR2010	10:20	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	21.8	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	70	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	030	8	V1 (WEEK 0)	1	25MAR2010	10:20	SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	61	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	5.41	mmol/L			< 6.50
							TRIGLYCERIDES	2.5	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	345	µmol/L			< 357
			V3 (WEEK 12)	85	17JUN2010	11:50	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	5.2	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	23.2	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	69	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	4.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE PHOSPHATASE	56	U/L			35 - 105

NCS=not clinically significant, CS=clinically significant

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	030	8	V3 (WEEK 12)	85	17JUN2010	11:50	GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	5.1	mmol/L			< 6.50
							TRIGLYCERIDES	1.76	mmol/L			0.57 - 2.28
							URIC ACID	363	µmol/L	HIGH	NCS	< 357
			V4 (WEEK 24)	163	03SEP2010	12:30	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	22.5	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	76	µmol/L			< 97
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	6.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 35
							SGPT (ALT)	39	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	58	U/L			35 - 105
							GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	6.92	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.41	mmol/L			0.57 - 2.28

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	030	8	V4 (WEEK 24)	163	03SEP2010	12:30	URIC ACID	393	µmol/L	HIGH	NCS	< 357
			V5 (WEEK 36)	253	02DEC2010	12:50	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	72.5	µmol/L			45.1 - 84.0
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	61	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	6.66	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.73	mmol/L			0.57 - 2.28
							URIC ACID	357	µmol/L	HIGH	NCS	< 357
			V6 (WEEK 52)	355	14MAR2011	11:00	SODIUM	149	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	030	8	V6 (WEEK 52)	355	14MAR2011	11:00	CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	26.6	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	76	µmol/L			45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35
							ALKALINE	56	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	6.45	mmol/L			< 6.50
							TRIGLYCERIDES	2.79	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	399	µmol/L			< 357
			V7 (WEEK 56)	383	11APR2011	11:30	SODIUM	148	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	23.9	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	030	8	V7 (WEEK 56)	383	11APR2011	11:30	CREATININE	81.3	µmol/L			45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.6	mmol/L			0.8 - 1.6
							GLUCOSE	4.11	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	48.9	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 35
							SGPT (ALT)	48	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	68	U/L			35 - 105
							GAMMA-GT	23	U/L			< 40
							CHOLESTEROL	6.42	mmol/L			< 6.50
							TRIGLYCERIDES	3.73	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	345	µmol/L			< 357
	032	8	SCREENING	-10	08NOV2010	10:00	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.8	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	55.7	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	032	8	SCREENING	-10	08NOV2010	10:00	PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	58	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.66	mmol/L	HIGH	CS	< 6.50
							TRIGLYCERIDES	1.01	mmol/L			0.57 - 2.28
							URIC ACID	202	µmol/L			< 357
							T3	1.4	nmol/L			1.2 - 3.1
							T4	100.6	nmol/L			65.8 - 182
							TSH	0.81	mU/L			0.27 - 4.20
							B12	272	pmol/L			145 - 639
							FOLATE	12.7	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1	U/L			< 5.0
			V1 (WEEK 0)	1	18NOV2010	10:10	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	032	8	V1 (WEEK 0)	1	18NOV2010	10:10	UREA	6.51	mmol/L			< 8.40
							CREATININE	60.1	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35
			V3 (WEEK 12)	82	07FEB2011	12:23	ALKALINE	56	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.37	mmol/L			< 6.50
							TRIGLYCERIDES	1.04	mmol/L			0.57 - 2.28
							URIC ACID	214	µmol/L			< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	5.2	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	31.1	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	61.9	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	032	8	V3 (WEEK 12)	82	07FEB2011	12:23	PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	46.3	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	60	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	7.46	mmol/L	HIGH	CS	< 6.50
							TRIGLYCERIDES	1.72	mmol/L			0.57 - 2.28
							URIC ACID	190	µmol/L			< 357
	033	9	SCREENING	-7	28OCT2009	8:15	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.7	mmol/L			3.6 - 5.4
							CHLORIDE	93	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	23.1	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	66	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	033	9	SCREENING	-7	28OCT2009	8:15	TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	78	g/L			61.0 - 81.0
							ALBUMIN	43.6	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE PHOSPHATASE	128	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	30	U/L			< 40
							CHOLESTEROL	6.4	mmol/L			< 6.50
							TRIGLYCERIDES	1.62	mmol/L			0.57 - 2.28
							URIC ACID	488	µmol/L	HIGH	NCS	< 357
							T3	1.94	nmol/L			1.2 - 3.1
							T4	136.7	nmol/L			65.8 - 182
							TSH	1	mU/L			0.27 - 4.20
							B12	189	pmol/L			145 - 639
							FOLATE	18.6	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	04NOV2009	8:00	BETA-HCG SERUM	2.6	U/L			< 5.0
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.4	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	58	µmol/L			< 97

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	033	9	V1 (WEEK 0)	1	04NOV2009	8:00	CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	31	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE PHOSPHATASE	126	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	24	U/L			< 40
							CHOLESTEROL	6.37	mmol/L			< 6.50
							TRIGLYCERIDES	2.54	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	387	µmol/L	HIGH	NCS	< 357
			V3 (WEEK 12)	78	20JAN2010	9:05	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.2	mmol/L	LOW	NCS	3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	55	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.84	mmol/L	HIGH	NCS	2.78 - 5.55

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	033	9	V3 (WEEK 12)	78	20JAN2010	9:05	TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	37	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	101	U/L			35 - 105
							GAMMA-GT	21	U/L			< 40
							CHOLESTEROL	6.37	mmol/L			< 6.50
							TRIGLYCERIDES	1.47	mmol/L			0.57 - 2.28
							URIC ACID	404	µmol/L	HIGH	NCS	< 357
		V4 (WEEK 24)		169	21APR2010	9:30	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.1	mmol/L	LOW	NCS	3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	65	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	43.1	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	033	9	V4 (WEEK 24)	169	21APR2010	9:30	SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	101	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	6.24	mmol/L			< 6.50
							TRIGLYCERIDES	1.55	mmol/L			0.57 - 2.28
							URIC ACID	446	µmol/L	HIGH	NCS	< 357
			V5 (WEEK 36)	261	22JUL2010	8:30	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	21.3	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	65	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	033	9	V5 (WEEK 36)	261	22JUL2010	8:30	ALKALINE PHOSPHATASE	102	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	7.1	mmol/L	HIGH	NCS	< 6.50
			V6 (WEEK 52)	372	10NOV2010	8:30	TRIGLYCERIDES	1.72	mmol/L			0.57 - 2.28
							URIC ACID	470	µmol/L	HIGH	NCS	< 357
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.6	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	65.4	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE PHOSPHATASE	110	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	23	U/L			< 40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	033	9	V6 (WEEK 52)	372	10NOV2010	8:30	CHOLESTEROL	5.21	mmol/L			< 6.50
							TRIGLYCERIDES	1.3	mmol/L			0.57 - 2.28
							URIC ACID	470	µmol/L	HIGH	NCS	< 357
			V7 (WEEK 56)	398	06DEC2010	8:45	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	24.3	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	68.1	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.11	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	99	U/L			35 - 105
							GAMMA-GT	23	U/L			< 40
							CHOLESTEROL	6.01	mmol/L			< 6.50
							TRIGLYCERIDES	1.8	mmol/L			0.57 - 2.28
							URIC ACID	458	µmol/L	HIGH	NCS	< 357

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	042	12	SCREENING	-29	16DEC2009	9:30	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	5.4	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	29.7	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	48	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	69	U/L			35 - 105
							GAMMA-GT	34	U/L			< 40
							CHOLESTEROL	5.05	mmol/L			< 6.50
							TRIGLYCERIDES	1.2	mmol/L			0.57 - 2.28
							URIC ACID	250	µmol/L			< 357
							T3	1.77	nmol/L			1.2 - 3.1
							T4	112.2	nmol/L			65.8 - 182
							TSH	1.02	mU/L			0.27 - 4.20

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	042	12	SCREENING	-29	16DEC2009	9:30	B12	337	pmol/L			145 - 639
							FOLATE	19.3	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	14JAN2010	9:15	BETA-HCG SERUM	1.8	U/L			< 5.0
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	23.5	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	50	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	54	U/L			35 - 105
							GAMMA-GT	29	U/L			< 40
							CHOLESTEROL	5.23	mmol/L			< 6.50
							TRIGLYCERIDES	1.37	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	042	12	V3 (WEEK 12)	126	19MAY2010	8:30	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	3.01	mmol/L			< 8.40
							CREATININE	71	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.12	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	46.9	g/L			35.0 - 55.0
							SGOT (AST)	49	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	86	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	57	U/L			35 - 105
							GAMMA-GT	25	U/L			< 40
							CHOLESTEROL	5.65	mmol/L			< 6.50
							TRIGLYCERIDES	1.44	mmol/L			0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
			V4 (WEEK 24)	168	30JUN2010	8:45	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	042	12	V4 (WEEK 24)	168	30JUN2010	8:45	BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	45.9	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 35
							SGPT (ALT)	50	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	56	U/L			35 - 105
							GAMMA-GT	30	U/L			< 40
							CHOLESTEROL	4.82	mmol/L			< 6.50
							TRIGLYCERIDES	1.3	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	252	22SEP2010	8:30	URIC ACID	238	µmol/L			< 357
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	5.4	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	66	µmol/L			< 97

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	042	12	V5 (WEEK 36)	252	22SEP2010	8:30	CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	6.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	78	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	28	U/L			< 35
							ALKALINE PHOSPHATASE	63	U/L			35 - 105
							GAMMA-GT	37	U/L			< 40
							CHOLESTEROL	7.72	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.52	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 357
			V6 (WEEK 52)	364	12JAN2011	8:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	26.1	mmol/L			22.0 - 29.0
							UREA	3.34	mmol/L			< 8.40
							CREATININE	67.2	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.45	mmol/L			2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	042	12	V6 (WEEK 52)	364	12JAN2011	8:30	TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	45.3	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	29	U/L			< 35
							ALKALINE PHOSPHATASE	66	U/L			35 - 105
							GAMMA-GT	37	U/L			< 40
							CHOLESTEROL	8.21	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.37	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 357
			V7 (WEEK 56)	391	08FEB2011	8:40	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25.7	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	61	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	6.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	042	12	V7 (WEEK 56)	391	08FEB2011	8:40	SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	60	U/L			35 - 105
							GAMMA-GT	30	U/L			< 40
							CHOLESTEROL	7.49	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.24	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 357
	043	12	SCREENING	-28	21OCT2009	9:45	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	22.8	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	65	µmol/L			< 106
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	7.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	38	U/L			10 - 50
							SGPT (ALT)	32	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	043	12	SCREENING	-28	21OCT2009	9:45	ALKALINE PHOSPHATASE	70	U/L			40 - 130
							GAMMA-GT	29	U/L			< 60
							CHOLESTEROL	4.45	mmol/L			< 6.50
							TRIGLYCERIDES	1.7	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 416
							T3	1.43	nmol/L			1.2 - 3.1
							T4	82.6	nmol/L			65.8 - 182
							TSH	1.2	mU/L			0.27 - 4.20
							B12	523	pmol/L			145 - 639
							FOLATE	17.9	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	18NOV2009	9:30	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.8	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	67	µmol/L			< 106
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	6.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	043	12	V1 (WEEK 0)	1	18NOV2009	9:30	SGOT (AST)	48	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE PHOSPHATASE	64	U/L			40 - 130
							GAMMA-GT	25	U/L			< 60
							CHOLESTEROL	4.22	mmol/L			< 6.50
							TRIGLYCERIDES	1.71	mmol/L			0.57 - 2.28
							URIC ACID	286	µmol/L			< 416
			V3 (WEEK 12)	85	10FEB2010	9:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	88	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	53	U/L	HIGH	NCS	10 - 50
							SGPT (ALT)	49	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	043	12	V3 (WEEK 12)	85	10FEB2010	9:30	ALKALINE PHOSPHATASE	58	U/L			40 - 130
			V4 (WEEK 24)	176	12MAY2010	9:00	GAMMA-GT	19	U/L			< 60
							CHOLESTEROL	4.77	mmol/L			< 6.50
							TRIGLYCERIDES	1.25	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 416
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	22.3	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	44.7	g/L			35.0 - 55.0
							SGOT (AST)	36	U/L			10 - 50
							SGPT (ALT)	38	U/L			< 50
							ALKALINE PHOSPHATASE	66	U/L			40 - 130
							GAMMA-GT	19	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	043	12	V4 (WEEK 24)	176	12MAY2010	9:00	CHOLESTEROL	4.33	mmol/L			< 6.50
							TRIGLYCERIDES	1.56	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 416
	046	11	SCREENING	-28	14DEC2009	9:30	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	25.9	mmol/L			22.0 - 29.0
							UREA	13.69	mmol/L	HIGH	CS	< 8.40
							CREATININE	146	µmol/L	HIGH	CS	< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	105	U/L			35 - 105
							GAMMA-GT	64	U/L	HIGH	NCS	< 40
							CHOLESTEROL	9.14	mmol/L	HIGH	CS	< 6.50
							TRIGLYCERIDES	2.68	mmol/L	HIGH	NCS	0.57 - 2.28

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	046	11	SCREENING	-28	14DEC2009	9:30	URIC ACID	381	µmol/L	HIGH	NCS	< 357
							T3	1.06	nmol/L	LOW	NCS	1.2 - 3.1
							T4	92.9	nmol/L			65.8 - 182
							TSH	1.55	mU/L			0.27 - 4.20
							B12	193	pmol/L			145 - 639
							FOLATE	12.7	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	17	U/L	HIGH	NCS	< 5.0
			V1 (WEEK 0)	1	11JAN2010	9:45	SODIUM	130	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	90	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	20.6	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	7.35	mmol/L			< 8.40
							CREATININE	103	µmol/L	HIGH	NCS	< 97
							CALCIUM	2.1	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	38	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	10	U/L			< 35
							ALKALINE PHOSPHATASE	153	U/L	HIGH	NCS	35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	046	11	V1 (WEEK 0)	1	11JAN2010	9:45	GAMMA-GT	51	U/L	HIGH	NCS	< 40
							CHOLESTEROL	7.23	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.12	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 357
			V3 (WEEK 12)	87	07APR2010	9:30	SODIUM	131	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	19	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	12.02	mmol/L	HIGH	NCS	< 8.40
							CREATININE	117	µmol/L	HIGH	NCS	< 97
							CALCIUM	2.1	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	6.51	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	59	g/L	LOW	NCS	61.0 - 81.0
							ALBUMIN	39.7	g/L			35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 35
							SGPT (ALT)	10	U/L			< 35
							ALKALINE	75	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	24	U/L			< 40
							CHOLESTEROL	6.73	mmol/L	HIGH	NCS	< 6.50
TRIGLYCERIDES	1.29	mmol/L			0.57 - 2.28							

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	046	11	V3 (WEEK 12)	87	07APR2010	9:30	URIC ACID	280	µmol/L			< 357
			V4 (WEEK 24)	178	07JUL2010	9:30	SODIUM	133	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	93	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	23.7	mmol/L			22.0 - 29.0
							UREA	9.35	mmol/L	HIGH	NCS	< 8.40
							CREATININE	111	µmol/L	HIGH	NCS	< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	11	U/L			< 35
							ALKALINE PHOSPHATASE	73	U/L			35 - 105
							GAMMA-GT	24	U/L			< 40
							CHOLESTEROL	6.09	mmol/L			< 6.50
							TRIGLYCERIDES	1.68	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
			V5 (WEEK 36)	255	22SEP2010	11:40	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	5.9	mmol/L	HIGH	NCS	3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	046	11	V5 (WEEK 36)	255	22SEP2010	11:40	CHLORIDE	93	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	24.4	mmol/L			22.0 - 29.0
							UREA	9.69	mmol/L	HIGH	NCS	< 8.40
							CREATININE	132	µmol/L	HIGH	CS	< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	7.9	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 35
							SGPT (ALT)	11	U/L			< 35
							ALKALINE	74	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	7.07	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.49	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	321	µmol/L			< 357
			V6 (WEEK 52)	367	12JAN2011	8:00	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0
							UREA	9.35	mmol/L	HIGH	NCS	< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	046	11	V6 (WEEK 52)	367	12JAN2011	8:00	CREATININE	118.5	µmol/L	HIGH	CS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	39.2	g/L			35.0 - 55.0
							SGOT (AST)	16	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	83	U/L			35 - 105
							GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	6.29	mmol/L			< 6.50
							TRIGLYCERIDES	0.88	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	393	07FEB2011	8:15	URIC ACID	369	µmol/L	HIGH	NCS	< 357
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	12.36	mmol/L	HIGH	NCS	< 8.40
							CREATININE	156.5	µmol/L	HIGH	CS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range		
					Date	Time								
ACI-91	046	11	V7 (WEEK 56)	393	07FEB2011	8:15	GLUCOSE	6.12	mmol/L	HIGH	NCS	2.78 - 5.55		
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0		
							TOTAL PROTEIN	64	g/L			61.0 - 81.0		
							ALBUMIN	41	g/L			35.0 - 55.0		
							SGOT (AST)	20	U/L			10 - 35		
							SGPT (ALT)	16	U/L			< 35		
							ALKALINE	78	U/L			35 - 105		
							PHOSPHATASE							
							GAMMA-GT	27	U/L			< 40		
							CHOLESTEROL	7.38	mmol/L			HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.17	mmol/L					0.57 - 2.28
	URIC ACID	399	µmol/L	HIGH	NCS	< 357								
	048	11	SCREENING	-5	17NOV2010	11:10	SODIUM	143	mmol/L			135 - 150		
							POTASSIUM	4.4	mmol/L			3.6 - 5.4		
							CHLORIDE	101	mmol/L			95 - 105		
							BICARBONATE	30.3	mmol/L	HIGH	NCS	22.0 - 29.0		
							UREA	5.34	mmol/L			< 8.40		
							CREATININE	99	µmol/L			59.2 - 103.4		
							CALCIUM	2.5	mmol/L			2.1 - 2.7		
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6		
							GLUCOSE	7.56	mmol/L	HIGH	NCS	2.78 - 5.55		
TOTAL BILIRUBIN							12	µmol/L	< 17.0					

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	048	11	SCREENING	-5	17NOV2010	11:10	TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 50
							SGPT (ALT)	23	U/L			< 50
							ALKALINE PHOSPHATASE	44	U/L			40 - 130
							GAMMA-GT	17	U/L			< 60
							CHOLESTEROL	5.52	mmol/L			< 6.50
							TRIGLYCERIDES	2.59	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	387	µmol/L			< 416
							T3	1.43	nmol/L			1.2 - 3.1
							T4	77.4	nmol/L			65.8 - 182
							TSH	2.06	mU/L			0.27 - 4.20
							BI2	262	pmol/L			145 - 639
							FOLATE	17.2	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	22NOV2010	10:30	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	104.3	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	048	11	V1 (WEEK 0)	1	22NOV2010	10:30	GLUCOSE	6.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	78	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 50
							SGPT (ALT)	32	U/L			< 50
							ALKALINE PHOSPHATASE	51	U/L			40 - 130
							GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	6.5	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.36	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	410	µmol/L			< 416
			V3 (WEEK 12)	86	15FEB2011	11:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	26.9	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	108.7	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	048	11	V3 (WEEK 12)	86	15FEB2011	11:00	ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE PHOSPHATASE	43	U/L			40 - 130
							GAMMA-GT	17	U/L			< 60
							CHOLESTEROL	4.9	mmol/L			< 6.50
							TRIGLYCERIDES	2.71	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	440	µmol/L	HIGH	NCS	< 416
			V4 (WEEK 24)	176	16MAY2011	10:30	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	23.2	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	113.2	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	43.5	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	21	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	048	11	V4 (WEEK 24)	176	16MAY2011	10:30	ALKALINE PHOSPHATASE	41	U/L			40 - 130
							GAMMA-GT	18	U/L			< 60
							CHOLESTEROL	5.1	mmol/L			< 6.50
							TRIGLYCERIDES	1.64	mmol/L			0.57 - 2.28
							URIC ACID	446	µmol/L	HIGH	NCS	< 416
			V5 (WEEK 36)	247	26JUL2011	10:40	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	102.5	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	6.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	39	U/L	LOW	NCS	40 - 130
							GAMMA-GT	16	U/L			< 60

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	048	11	V5 (WEEK 36)	247	26JUL2011	10:40	CHOLESTEROL	5.13	mmol/L			< 6.50
			V6 (WEEK 52)	360	16NOV2011	10:00	TRIGLYCERIDES	2.49	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	434	µmol/L	HIGH	NCS	< 416
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	27.2	mmol/L			22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	107	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	7.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	17	U/L			< 50
							ALKALINE PHOSPHATASE	41	U/L			40 - 130
							GAMMA-GT	15	U/L			< 60
							CHOLESTEROL	4.87	mmol/L			< 6.50
							TRIGLYCERIDES	2.85	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	404	µmol/L			< 416

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	048	11	V7 (WEEK 56)	395	21DEC2011	11:20	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.1	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	107.8	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	8.01	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	45.3	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 50
							SGPT (ALT)	38	U/L			< 50
							ALKALINE PHOSPHATASE	48	U/L			40 - 130
							GAMMA-GT	22	U/L			< 60
							CHOLESTEROL	5.44	mmol/L			< 6.50
							TRIGLYCERIDES	3.55	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	422	µmol/L	HIGH	NCS	< 416
	050	21	SCREENING	-51	06SEP2010	14:30	SODIUM	137	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	050	21	SCREENING	-51	06SEP2010	14:30	CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	23.5	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	82	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	51	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE	93	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	25	U/L			< 40
							CHOLESTEROL	8	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.03	mmol/L			0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
							T3	1.32	nmol/L			1.2 - 3.1
							T4	89	nmol/L			65.8 - 182
							TSH	1.16	mU/L			0.27 - 4.20
							B12	286	pmol/L			145 - 639
							FOLATE	14.9	nmol/L			10.4 - 42.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	050	21	SCREENING V1 (WEEK 0)	-51 1	06SEP2010 27OCT2010	14:30 11:45	BETA-HCG SERUM	1	U/L			< 5.0
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0
							UREA	6.85	mmol/L			< 8.40
							CREATININE	85.7	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	80	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	6.73	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.44	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
			V3 (WEEK 12)	83	17JAN2011	11:15	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	050	21	V3 (WEEK 12)	83	17JAN2011	11:15	CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	89.3	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE	87	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	7.51	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.07	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 357
			V4 (WEEK 24)	167	11APR2011	11:20	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	24	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	050	21	V4 (WEEK 24)	167	11APR2011	11:20	CREATININE	88.4	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	44.4	g/L			35.0 - 55.0
							SGOT (AST)	37	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	32	U/L			< 35
							ALKALINE PHOSPHATASE	85	U/L			35 - 105
							GAMMA-GT	20	U/L			< 40
							CHOLESTEROL	7.2	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.65	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	251	04JUL2011	11:50	URIC ACID	256	µmol/L			< 357
							SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	25	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	85.7	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	050	21	V5 (WEEK 36)	251	04JUL2011	11:50	GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L		< 17.0	
							TOTAL PROTEIN	70	g/L		61.0 - 81.0	
							ALBUMIN	43.1	g/L		35.0 - 55.0	
							SGOT (AST)	35	U/L		10 - 35	
							SGPT (ALT)	22	U/L		< 35	
							ALKALINE	101	U/L		35 - 105	
							PHOSPHATASE					
							GAMMA-GT	22	U/L		< 40	
							CHOLESTEROL	7.02	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.56	mmol/L			0.57 - 2.28
			URIC ACID	220	µmol/L		< 357					
			V6 (WEEK 52)	363	24OCT2011	9:00	SODIUM	141	mmol/L		135 - 150	
							POTASSIUM	4.2	mmol/L		3.6 - 5.4	
							CHLORIDE	103	mmol/L		95 - 105	
							BICARBONATE	28	mmol/L		22.0 - 29.0	
							UREA	5.18	mmol/L		< 8.40	
							CREATININE	73.4	µmol/L		45.1 - 84.0	
							CALCIUM	2.3	mmol/L		2.1 - 2.7	
							PHOSPHATE	1.2	mmol/L		0.8 - 1.6	
							GLUCOSE	4.17	mmol/L		2.78 - 5.55	
							TOTAL BILIRUBIN	8.6	µmol/L		< 17.0	
TOTAL PROTEIN	66	g/L						61.0 - 81.0				

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	050	21	V6 (WEEK 52)	363	24OCT2011	9:00	ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	94	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	7.1	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.55	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	391	21NOV2011	8:51	URIC ACID	220	µmol/L			< 357
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	25.5	mmol/L			22.0 - 29.0
							UREA	7.52	mmol/L			< 8.40
							CREATININE	83.1	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	4.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	61	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	11	U/L			< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	050	21	V7 (WEEK 56)	391	21NOV2011	8:51	ALKALINE PHOSPHATASE	102	U/L			35 - 105
							GAMMA-GT	21	U/L			< 40
							CHOLESTEROL	7.12	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.02	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 357
	052	21	SCREENING	-52	06SEP2010	14:15	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	20.9	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	3.34	mmol/L			< 8.40
							CREATININE	80	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	152	U/L	HIGH	NCS	35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	052	21	SCREENING	-52	06SEP2010	14:15	GAMMA-GT	153	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.05	mmol/L			< 6.50
							TRIGLYCERIDES	0.87	mmol/L			0.57 - 2.28
							URIC ACID	363	µmol/L	HIGH	NCS	< 357
							T3	1.63	nmol/L			1.2 - 3.1
							T4	91.6	nmol/L			65.8 - 182
							TSH	0.75	mU/L			0.27 - 4.20
							Bl2	102	pmol/L	LOW	CS	145 - 639
							FOLATE	12.2	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1.9	U/L			< 5.0
			V1 (WEEK 0)	1	28OCT2010	8:15	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	72.5	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	44.8	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	052	21	V1 (WEEK 0)	1	28OCT2010	8:15	SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	158	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	175	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.7	mmol/L			< 6.50
							TRIGLYCERIDES	1.06	mmol/L			0.57 - 2.28
							URIC ACID	333	µmol/L			< 357
			V3 (WEEK 12)	82	17JAN2011	10:45	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	24.5	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	72.5	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	79	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	148	U/L	HIGH	NCS	35 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	052	21	V3 (WEEK 12)	82	17JAN2011	10:45	GAMMA-GT	149	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.36	mmol/L			< 6.50
							TRIGLYCERIDES	0.71	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 357
			V4 (WEEK 24)	166	11APR2011	10:45	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	73.4	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	40.5	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	156	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	168	U/L	HIGH	NCS	< 40
							CHOLESTEROL	4.95	mmol/L			< 6.50
							TRIGLYCERIDES	1	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	052	21	V4 (WEEK 24)	166	11APR2011	10:45	URIC ACID	309	µmol/L			< 357
			V5 (WEEK 36)	250	04JUL2011	9:24	SODIUM	135	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	24.3	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	78.7	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	40.6	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	152	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	160	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.05	mmol/L			< 6.50
							TRIGLYCERIDES	0.97	mmol/L			0.57 - 2.28
							URIC ACID	327	µmol/L			< 357
			V6 (WEEK 52)	362	24OCT2011	12:15	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	052	21	V6 (WEEK 52)	362	24OCT2011	12:15	CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	67.2	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE	135	U/L	HIGH	NCS	35 - 105
							PHOSPHATASE					
							GAMMA-GT	160	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.13	mmol/L			< 6.50
							TRIGLYCERIDES	1.01	mmol/L			0.57 - 2.28
							URIC ACID	315	µmol/L			< 357
			V7 (WEEK 56)	390	21NOV2011	9:46	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	24.9	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	052	21	V7 (WEEK 56)	390	21NOV2011	9:46	CREATININE	76	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	150	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	143	U/L	HIGH	NCS	< 40
							CHOLESTEROL	4.71	mmol/L			< 6.50
							TRIGLYCERIDES	0.78	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
	055	5	SCREENING	-21	08MAR2010	11:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	90	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	055	5	SCREENING	-21	08MAR2010	11:30	PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45.6	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE PHOSPHATASE	76	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	5.23	mmol/L			< 6.50
							TRIGLYCERIDES	3.53	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	315	µmol/L			< 357
							T3	1.43	nmol/L			1.2 - 3.1
							T4	90.3	nmol/L			65.8 - 182
							TSH	3.7	mU/L			0.27 - 4.20
							B12	220	pmol/L			145 - 639
							FOLATE	9.7	nmol/L	LOW	NCS	10.4 - 42.4
							BETA-HCG SERUM	9.8	U/L	HIGH	NCS	< 5.0
			V1 (WEEK 0)	1	29MAR2010	9:30	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	22.8	mmol/L			22.0 - 29.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	055	5	V1 (WEEK 0)	1	29MAR2010	9:30	UREA	5.01	mmol/L			< 8.40
							CREATININE	97	µmol/L	HIGH	NCS	< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	42.1	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	76	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	5.72	mmol/L			< 6.50
							TRIGLYCERIDES	2.21	mmol/L			0.57 - 2.28
			V6 (WEEK 52)	30	27APR2010	9:15	URIC ACID	375	µmol/L	HIGH	NCS	< 357
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	22.9	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	88	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	055	5	V6 (WEEK 52)	30	27APR2010	9:15	PHOSPHATE	0.9	mmol/L	HIGH	NCS	0.8 - 1.6
							GLUCOSE	6.51	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	42.7	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	78	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	6.11	mmol/L			< 6.50
							TRIGLYCERIDES	2.87	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	339	µmol/L			< 357
	057	1	SCREENING	-21	29JUL2010	10:50	SODIUM	137	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	27	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	80	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	057	1	SCREENING	-21	29JUL2010	10:50	TOTAL BILIRUBIN	1.7	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0
							ALBUMIN	40	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	91	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	5.7	mmol/L			< 6.50
							TRIGLYCERIDES	0.86	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 357
							T3	1.62	nmol/L			1.2 - 3.1
							T4	82.6	nmol/L			65.8 - 182
							TSH	0.88	mU/L			0.27 - 4.20
							B12	213	pmol/L			145 - 639
							FOLATE	26.7	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	19AUG2010	11:10	BETA-HCG SERUM	3	U/L			< 5.0
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	23.1	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	91	µmol/L			< 97

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	057	1	V1 (WEEK 0)	1	19AUG2010	11:10	CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.11	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	35	U/L			10 - 35
							SGPT (ALT)	39	U/L	HIGH	NCS	< 35
							ALKALINE	95	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.66	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.45	mmol/L			0.57 - 2.28
							URIC ACID	315	µmol/L			< 357
			V3 (WEEK 12)	82	08NOV2010	9:45	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	10.52	mmol/L	HIGH	NCS	< 8.40
							CREATININE	80.4	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.45	mmol/L			2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	057	1	V3 (WEEK 12)	82	08NOV2010	9:45	TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	40	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	34	U/L			< 35
							ALKALINE PHOSPHATASE	91	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	6.5	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.12	mmol/L			0.57 - 2.28
							URIC ACID	309	µmol/L			< 357
			V4 (WEEK 24)	170	04FEB2011	9:35	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	26.4	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	76	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	61	g/L			61.0 - 81.0
							ALBUMIN	39	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	057	1	V4 (WEEK 24)	170	04FEB2011	9:35	SGOT (AST)	40	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	55	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	85	U/L			35 - 105
							GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	6.5	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.93	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
	066	16	SCREENING	-31	09AUG2010	10:40	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	18.2	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	90	µmol/L			< 106
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	38	g/L			35.0 - 55.0
							SGOT (AST)	35	U/L			10 - 50
							SGPT (ALT)	36	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	066	16	SCREENING	-31	09AUG2010	10:40	ALKALINE PHOSPHATASE	104	U/L			40 - 130
							GAMMA-GT	199	U/L	HIGH	NCS	< 60
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	1.03	mmol/L			0.57 - 2.28
							URIC ACID	309	µmol/L			< 416
							T3	1.51	nmol/L			1.2 - 3.1
							T4	90.3	nmol/L			65.8 - 182
							TSH	0.72	mU/L			0.27 - 4.20
							B12	139	pmol/L	LOW	NCS	145 - 639
							FOLATE	19.9	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	09SEP2010	9:25	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	22.6	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	95	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	40.9	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	066	16	V1 (WEEK 0)	1	09SEP2010	9:25	SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	33	U/L			< 50
							ALKALINE PHOSPHATASE	110	U/L			40 - 130
							GAMMA-GT	203	U/L	HIGH	NCS	< 60
							CHOLESTEROL	4.71	mmol/L			< 6.50
							TRIGLYCERIDES	1.38	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	83	30NOV2010	9:15	URIC ACID	303	µmol/L			< 416
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	105.2	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	37.3	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	24	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	066	16	V3 (WEEK 12)	83	30NOV2010	9:15	ALKALINE PHOSPHATASE	96	U/L			40 - 130
							GAMMA-GT	164	U/L	HIGH	NCS	< 60
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	1.35	mmol/L			0.57 - 2.28
							URIC ACID	297	µmol/L			< 416
	067	16	SCREENING	-16	02NOV2010	10:40	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	24.4	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	88.4	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	105	U/L			35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	067	16	SCREENING	-16	02NOV2010	10:40	GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	5.02	mmol/L			< 6.50
							TRIGLYCERIDES	0.86	mmol/L			0.57 - 2.28
							URIC ACID	315	µmol/L			< 357
							T3	1.72	nmol/L			1.2 - 3.1
							T4	83.9	nmol/L			65.8 - 182
							TSH	1.53	mU/L			0.27 - 4.20
							B12	283	pmol/L			145 - 639
							FOLATE	18.1	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	4.6	U/L			< 5.0
			V1 (WEEK 0)	1	18NOV2010	8:30	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	28.6	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	84.9	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	43	g/L		NCS	35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	067	16	V1 (WEEK 0)	1	18NOV2010	8:30	SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	101	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	5.8	mmol/L			< 6.50
							TRIGLYCERIDES	0.88	mmol/L			0.57 - 2.28
							URIC ACID	315	µmol/L			< 357
			V6 (WEEK 52)	69	25JAN2011	10:50	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	27	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	76.9	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	106	U/L	HIGH	NCS	35 - 105

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Listing 16.2.8.2: Biochemistry

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range			
					Date	Time									
ACI-91	067	16	V6 (WEEK 52)	69	25JAN2011	10:50	GAMMA-GT	11	U/L			< 40			
							CHOLESTEROL	5.46	mmol/L		< 6.50				
							TRIGLYCERIDES	1.86	mmol/L		0.57 - 2.28				
						V7 (WEEK 56)	111	08MAR2011	9:05	URIC ACID	327	µmol/L		< 357	
			SODIUM	143	mmol/L						135 - 150				
			POTASSIUM	4.8	mmol/L						3.6 - 5.4				
										CHLORIDE	101	mmol/L		95 - 105	
										BICARBONATE	25.1	mmol/L		22.0 - 29.0	
										UREA	3.84	mmol/L		< 8.40	
										CREATININE	87.5	µmol/L	HIGH	NCS	45.1 - 84.0
										CALCIUM	2.3	mmol/L			2.1 - 2.7
										PHOSPHATE	1	mmol/L			0.8 - 1.6
										GLUCOSE	7.01	mmol/L	HIGH	NCS	2.78 - 5.55
										TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
										TOTAL PROTEIN	74	g/L			61.0 - 81.0
										ALBUMIN	44	g/L			35.0 - 55.0
										SGOT (AST)	24	U/L			10 - 35
										SGPT (ALT)	25	U/L			< 35
										ALKALINE	102	U/L			35 - 105
										PHOSPHATASE					
										GAMMA-GT	13	U/L			< 40
										CHOLESTEROL	5.13	mmol/L			< 6.50
							TRIGLYCERIDES	2.18	mmol/L			0.57 - 2.28			

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Listing 16.2.8.2: Biochemistry

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	067	16	V7 (WEEK 56)	111	08MAR2011	9:05	URIC ACID	345	µmol/L			< 357
	071	18	SCREENING	-20	20OCT2010	10:05	SODIUM	143	mmol/L		NCS	135 - 150
							POTASSIUM	3.8	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	96	mmol/L		NCS	95 - 105
							BICARBONATE	27.3	mmol/L		NCS	22.0 - 29.0
							UREA	5.01	mmol/L		NCS	< 8.40
							CREATININE	60.1	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.2	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	9.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	71	g/L		NCS	61.0 - 81.0
							ALBUMIN	48	g/L		NCS	35.0 - 55.0
							SGOT (AST)	20	U/L		NCS	10 - 35
							SGPT (ALT)	17	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	75	U/L		NCS	35 - 105
							GAMMA-GT	16	U/L		NCS	< 40
							CHOLESTEROL	5.54	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	0.76	mmol/L		NCS	0.57 - 2.28
							URIC ACID	214	µmol/L		NCS	< 357
							T3	1.37	nmol/L		NCS	1.2 - 3.1

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	071	18	SCREENING	-20	20OCT2010	10:05	T4	126.4	nmol/L		NCS	65.8 - 182
							TSH	0.29	mU/L		NCS	0.27 - 4.20
							B12	192	pmol/L		NCS	145 - 639
							FOLATE	22.2	nmol/L		NCS	10.4 - 42.4
							BETA-HCG SERUM	1.5	U/L		NCS	< 5.0
			V1 (WEEK 0)	1	09NOV2010	11:00	SODIUM	143	mmol/L		NCS	135 - 150
							POTASSIUM	4.3	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	99	mmol/L		NCS	95 - 105
							BICARBONATE	27	mmol/L		NCS	22.0 - 29.0
							UREA	4.01	mmol/L		NCS	< 8.40
							CREATININE	65.4	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.2	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	5.12	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	75	g/L		NCS	61.0 - 81.0
							ALBUMIN	50	g/L		NCS	35.0 - 55.0
							SGOT (AST)	23	U/L		NCS	10 - 35
							SGPT (ALT)	23	U/L		NCS	< 35
							ALKALINE	76	U/L		NCS	35 - 105
							PHOSPHATASE					
							GAMMA-GT	18	U/L		NCS	< 40
							CHOLESTEROL	6.48	mmol/L		NCS	< 6.50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	071	18	V1 (WEEK 0)	1	09NOV2010	11:00	TRIGLYCERIDES	1.3	mmol/L		NCS	0.57 - 2.28
							URIC ACID	256	µmol/L		NCS	< 357
			V3 (WEEK 12)	87	03FEB2011	10:07	SODIUM	142	mmol/L		NCS	135 - 150
							POTASSIUM	3.7	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	100	mmol/L		NCS	95 - 105
							BICARBONATE	24.5	mmol/L		NCS	22.0 - 29.0
							UREA	4.01	mmol/L		NCS	< 8.40
							CREATININE	62.8	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	0.9	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	5.17	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	67	g/L		NCS	61.0 - 81.0
							ALBUMIN	49	g/L		NCS	35.0 - 55.0
							SGOT (AST)	30	U/L		NCS	10 - 35
							SGPT (ALT)	55	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	132	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	262	U/L	HIGH	CS	< 40
							CHOLESTEROL	5.44	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	0.86	mmol/L		NCS	0.57 - 2.28
							URIC ACID	202	µmol/L		NCS	< 357
			V4 (WEEK 24)	177	04MAY2011	9:35	SODIUM	142	mmol/L		NCS	135 - 150

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	071	18	V4 (WEEK 24)	177	04MAY2011	9:35	POTASSIUM	4.3	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	97	mmol/L		NCS	95 - 105
							BICARBONATE	26.3	mmol/L		NCS	22.0 - 29.0
							UREA	4.01	mmol/L		NCS	< 8.40
							CREATININE	62.8	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.2	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	5.06	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	70	g/L		NCS	61.0 - 81.0
							ALBUMIN	47.8	g/L		NCS	35.0 - 55.0
							SGOT (AST)	21	U/L		NCS	10 - 35
							SGPT (ALT)	26	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	89	U/L		NCS	35 - 105
							GAMMA-GT	62	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.39	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	0.76	mmol/L		NCS	0.57 - 2.28
							URIC ACID	244	µmol/L		NCS	< 357
			V5 (WEEK 36)	253	19JUL2011	9:41	SODIUM	140	mmol/L		NCS	135 - 150
							POTASSIUM	4.6	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	102	mmol/L		NCS	95 - 105
							BICARBONATE	21.9	mmol/L	LOW	NCS	22.0 - 29.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	071	18	V5 (WEEK 36)	253	19JUL2011	9:41	UREA	5.34	mmol/L		NCS	< 8.40
							CREATININE	70.7	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	0.5	mmol/L	LOW	NCS	0.8 - 1.6
							GLUCOSE	6.45	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	18.8	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	70	g/L		NCS	61.0 - 81.0
							ALBUMIN	47	g/L		NCS	35.0 - 55.0
							SGOT (AST)	23	U/L		NCS	10 - 35
							SGPT (ALT)	23	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	78	U/L		NCS	35 - 105
							GAMMA-GT	50	U/L	HIGH	NCS	< 40
							CHOLESTEROL	6.09	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	0.89	mmol/L		NCS	0.57 - 2.28
							URIC ACID	226	µmol/L		NCS	< 357
			V6 (WEEK 52)	374	17NOV2011	11:02	SODIUM	142	mmol/L		NCS	135 - 150
							POTASSIUM	3.9	mmol/L		CS	3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	26	mmol/L		NCS	22.0 - 29.0
							UREA	4.01	mmol/L		NCS	< 8.40
							CREATININE	60.1	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L		NCS	2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	071	18	V6 (WEEK 52)	374	17NOV2011	11:02	PHOSPHATE	0.9	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	4.84	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	68	g/L		NCS	61.0 - 81.0
							ALBUMIN	48	g/L		NCS	35.0 - 55.0
							SGOT (AST)	17	U/L		NCS	10 - 35
							SGPT (ALT)	16	U/L		NCS	< 35
							ALKALINE	80	U/L		NCS	35 - 105
							PHOSPHATASE					
							GAMMA-GT	36	U/L		NCS	< 40
							CHOLESTEROL	5.31	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	0.98	mmol/L		NCS	0.57 - 2.28
							URIC ACID	232	µmol/L		NCS	< 357
		V7 (WEEK 56)	392	05DEC2011	12:01	SODIUM	140	mmol/L		NCS	135 - 150	
						POTASSIUM	4.8	mmol/L		NCS	3.6 - 5.4	
						CHLORIDE	103	mmol/L		NCS	95 - 105	
						BICARBONATE	24.8	mmol/L		NCS	22.0 - 29.0	
						UREA	4.84	mmol/L		NCS	< 8.40	
						CREATININE	67.2	µmol/L		NCS	45.1 - 84.0	
						CALCIUM	2.5	mmol/L		NCS	2.1 - 2.7	
						PHOSPHATE	0.8	mmol/L		NCS	0.8 - 1.6	
						GLUCOSE	5.28	mmol/L		NCS	2.78 - 5.55	
						TOTAL BILIRUBIN	10.3	µmol/L		NCS	< 17.0	

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	071	18	V7 (WEEK 56)	392	05DEC2011	12:01	TOTAL PROTEIN	72	g/L		NCS	61.0 - 81.0
							ALBUMIN	50	g/L		NCS	35.0 - 55.0
							SGOT (AST)	22	U/L		NCS	10 - 35
							SGPT (ALT)	25	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	88	U/L		NCS	35 - 105
							GAMMA-GT	40	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.96	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	0.87	mmol/L		NCS	0.57 - 2.28
							URIC ACID	244	µmol/L		NCS	< 357
	080	13	SCREENING	-10	08NOV2010	10:27	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.5	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	79.6	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	080	13	SCREENING	-10	08NOV2010	10:27	SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	94	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	7.38	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.79	mmol/L			0.57 - 2.28
							URIC ACID	333	µmol/L			< 357
							T3	1.22	nmol/L	LOW	NCS	1.2 - 3.1
							T4	95.5	nmol/L			65.8 - 182
							TSH	1.07	mU/L			0.27 - 4.20
							B12	286	pmol/L			145 - 639
							FOLATE	17.4	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	2.9	U/L			< 5.0
			V1 (WEEK 0)	1	18NOV2010	12:30	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	27.2	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	74.3	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	080	13	V1 (WEEK 0)	1	18NOV2010	12:30	TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	86	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.37	mmol/L			< 6.50
							TRIGLYCERIDES	1.01	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
			V3 (WEEK 12)	84	09FEB2011	11:30	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.5	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	76.9	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.62	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	080	13	V3 (WEEK 12)	84	09FEB2011	11:30	SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	75	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	7.15	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.06	mmol/L			0.57 - 2.28
							URIC ACID	291	µmol/L			< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	78.7	µmol/L			45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
		16	V6 (WEEK 52)	196	01JUN2011	12:30						

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	080	13	V6 (WEEK 52)	196	01JUN2011	12:30	ALKALINE PHOSPHATASE	70	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	7.51	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.04	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L	HIGH	NCS	< 357
	081	17	SCREENING	-10	04OCT2010	11:20	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	23.8	mmol/L			22.0 - 29.0
							UREA	7.85	mmol/L			< 8.40
							CREATININE	74.3	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	3.78	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	48.7	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	15	U/L			< 50
							ALKALINE PHOSPHATASE	65	U/L			40 - 130

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	081	17	SCREENING	-10	04OCT2010	11:20	GAMMA-GT	10	U/L			< 60
							CHOLESTEROL	6.94	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.55	mmol/L	LOW	NCS	0.57 - 2.28
							URIC ACID	297	µmol/L			< 416
							T3	1.51	nmol/L			1.2 - 3.1
							T4	132.9	nmol/L			65.8 - 182
							TSH	1.9	mU/L			0.27 - 4.20
							Bl2	156	pmol/L			145 - 639
							FOLATE	19.9	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	14OCT2010	10:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	83.1	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	6.12	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 50
							SGPT (ALT)	14	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	081	17	V1 (WEEK 0)	1	14OCT2010	10:00	ALKALINE PHOSPHATASE	69	U/L			40 - 130
			V3 (WEEK 12)	89	10JAN2011	11:15	GAMMA-GT	9	U/L			< 60
							CHOLESTEROL	6.6	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.15	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 416
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	26	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	77.8	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	47	g/L		NCS	35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 50
							SGPT (ALT)	10	U/L			< 50
							ALKALINE PHOSPHATASE	55	U/L			40 - 130
							GAMMA-GT	10	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	11:15	CHOLESTEROL	6.45	mmol/L			< 6.50
							TRIGLYCERIDES	0.68	mmol/L			0.57 - 2.28
							URIC ACID	262	µmol/L			< 416
			V4 (WEEK 24)	175	06APR2011	9:30	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	23.6	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	87.5	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	3.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	18	U/L			< 50
							ALKALINE PHOSPHATASE	68	U/L			40 - 130
							GAMMA-GT	16	U/L			< 60
							CHOLESTEROL	6.58	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.37	mmol/L			0.57 - 2.28
							URIC ACID	351	µmol/L			< 416

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	081	17	V5 (WEEK 36)	250	20JUN2011	11:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	27.1	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	78.7	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	18	U/L			< 50
							ALKALINE PHOSPHATASE	59	U/L			40 - 130
			V6 (WEEK 52)	376	24OCT2011	10:35	GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	6.94	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.03	mmol/L			0.57 - 2.28
							URIC ACID	286	µmol/L			< 416
							SODIUM	133	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	94	mmol/L	LOW	NCS	95 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	081	17	V6 (WEEK 52)	376	24OCT2011	10:35	BICARBONATE	25.7	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	55.7	µmol/L	LOW	NCS	59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	3.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 50
							SGPT (ALT)	8	U/L			< 50
							ALKALINE	74	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	13	U/L			< 60
							CHOLESTEROL	5.75	mmol/L			< 6.50
							TRIGLYCERIDES	0.63	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	405	22NOV2011	10:45	URIC ACID	190	µmol/L			< 416
							SODIUM	137	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	54.8	µmol/L	LOW	NCS	59.2 - 103.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	081	17	V7 (WEEK 56)	405	22NOV2011	10:45	CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	15	U/L			10 - 50
							SGPT (ALT)	10	U/L			< 50
							ALKALINE PHOSPHATASE	92	U/L			40 - 130
							GAMMA-GT	13	U/L			< 60
							CHOLESTEROL	5.67	mmol/L			< 6.50
							TRIGLYCERIDES	0.6	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 416
	083	17	SCREENING	-15	26OCT2010	11:30	SODIUM	135	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	94	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	21.3	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	80.4	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	083	17	SCREENING	-15	26OCT2010	11:30	GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	78	g/L			61.0 - 81.0
							ALBUMIN	52	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 35
							SGPT (ALT)	24	U/L			< 35
							ALKALINE PHOSPHATASE	98	U/L			35 - 105
							GAMMA-GT	30	U/L			< 40
							CHOLESTEROL	4.12	mmol/L			< 6.50
							TRIGLYCERIDES	1.14	mmol/L			0.57 - 2.28
							URIC ACID	399	µmol/L	HIGH	NCS	< 357
							T3	1.05	nmol/L	LOW	NCS	1.2 - 3.1
							T4	73.5	nmol/L			65.8 - 182
							TSH	2.66	mU/L			0.27 - 4.20
							B12	227	pmol/L			145 - 639
							FOLATE	14.7	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	12	U/L	HIGH	NCS	< 5.0
			V1 (WEEK 0)	1	10NOV2010	9:25	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	27.7	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	083	17	V1 (WEEK 0)	1	10NOV2010	9:25	CREATININE	86.6	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE PHOSPHATASE	76	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	3.96	mmol/L			< 6.50
							TRIGLYCERIDES	1.03	mmol/L			0.57 - 2.28
			V4 (WEEK 24)	168	26APR2011	10:15	URIC ACID	446	µmol/L	HIGH	NCS	< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	73.4	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	083	17	V4 (WEEK 24)	168	26APR2011	10:15	GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	71	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	5.7	mmol/L			< 6.50
							TRIGLYCERIDES	0.81	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 357
		V5 (WEEK 36)		258	25JUL2011	10:50	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	26.4	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	70.7	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	3.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	083	17	V5 (WEEK 36)	258	25JUL2011	10:50	ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	54	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	6.5	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.64	mmol/L			0.57 - 2.28
			V6 (WEEK 52)	365	09NOV2011	10:20	URIC ACID	202	µmol/L			< 357
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	27.3	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	97.2	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	0.5	mmol/L	LOW	NCS	0.8 - 1.6
							GLUCOSE	10.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	083	17	V6 (WEEK 52)	365	09NOV2011	10:20	ALKALINE PHOSPHATASE	86	U/L			35 - 105
							GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	3.94	mmol/L			< 6.50
							TRIGLYCERIDES	1.78	mmol/L			0.57 - 2.28
							URIC ACID	309	µmol/L			< 357
			V7 (WEEK 56)	392	06DEC2011	10:20	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.9	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	87.5	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.1	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	59	U/L			35 - 105
							GAMMA-GT	11	U/L			< 40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	083	17	V7 (WEEK 56)	392	06DEC2011	10:20	CHOLESTEROL	7.72	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.16	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 357
	087	16	SCREENING	-20	09NOV2010	9:05	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	24.3	mmol/L			22.0 - 29.0
							UREA	7.35	mmol/L			< 8.40
							CREATININE	91.1	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	9.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	83	g/L	HIGH	NCS	61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	27	U/L			< 35
							ALKALINE PHOSPHATASE	63	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	6.73	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.22	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	087	16	SCREENING	-20	09NOV2010	9:05	URIC ACID	345	µmol/L			< 357
							T3	1.54	nmol/L			1.2 - 3.1
							T4	113.5	nmol/L			65.8 - 182
							TSH	0.43	mU/L			0.27 - 4.20
							B12	201	pmol/L			145 - 639
							FOLATE	12.7	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	3	U/L			< 5.0
			V1 (WEEK 0)	1	29NOV2010	10:10	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0
							UREA	7.18	mmol/L			< 8.40
							CREATININE	89.3	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.89	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE	51	U/L			35 - 105
							PHOSPHATASE					

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	087	16	V1 (WEEK 0)	1	29NOV2010	10:10	GAMMA-GT	14	U/L			< 40
			V3 (WEEK 12)	81	17FEB2011	9:35	CHOLESTEROL	6.14	mmol/L			< 6.50
							TRIGLYCERIDES	1.17	mmol/L			0.57 - 2.28
							URIC ACID	351	µmol/L			< 357
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	26	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	86.6	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	7.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	81	g/L			61.0 - 81.0
							ALBUMIN	49.9	g/L			35.0 - 55.0
							SGOT (AST)	45	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	59	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	70	U/L			35 - 105
							GAMMA-GT	23	U/L			< 40
							CHOLESTEROL	6.73	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.23	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	087	16	V3 (WEEK 12)	81	17FEB2011	9:35	URIC ACID	399	µmol/L	HIGH	NCS	< 357
			V4 (WEEK 24)	169	16MAY2011	11:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	20.4	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	94.6	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	6.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	80	g/L			61.0 - 81.0
							ALBUMIN	47.1	g/L			35.0 - 55.0
							SGOT (AST)	38	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	42	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	68	U/L			35 - 105
							GAMMA-GT	21	U/L			< 40
							CHOLESTEROL	6.86	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.32	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	255	10AUG2011	10:20	URIC ACID	410	µmol/L	HIGH	NCS	< 357
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	087	16	V5 (WEEK 36)	255	10AUG2011	10:20	CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	21.8	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	93.7	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	7.12	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	81	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE	57	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	6.24	mmol/L			< 6.50
							TRIGLYCERIDES	1.62	mmol/L			0.57 - 2.28
			V6 (WEEK 52)	365	28NOV2011	10:15	URIC ACID	416	µmol/L	HIGH	NCS	< 357
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.7	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	087	16	V6 (WEEK 52)	365	28NOV2011	10:15	CREATININE	84	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	7.12	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	80	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	71	U/L			35 - 105
							GAMMA-GT	22	U/L			< 40
							CHOLESTEROL	7.33	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.77	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L	HIGH	NCS	< 357
			V7 (WEEK 56)	395	28DEC2011	12:00	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	96.4	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	087	16	V7 (WEEK 56)	395	28DEC2011	12:00	GLUCOSE	8.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	81	g/L			61.0 - 81.0
							ALBUMIN	48.8	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	26	U/L			< 35
							ALKALINE PHOSPHATASE	74	U/L			35 - 105
							GAMMA-GT	20	U/L			< 40
							CHOLESTEROL	7.2	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.01	mmol/L			0.57 - 2.28
							URIC ACID	357	µmol/L	HIGH	NCS	< 357
	089	5	SCREENING	-28	19OCT2010	12:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	27.8	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	84.9	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.11	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	089	5	SCREENING	-28	19OCT2010	12:00	TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	56	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.76	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.3	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 357
							T3	1.39	nmol/L			1.2 - 3.1
							T4	90.3	nmol/L			65.8 - 182
							TSH	0.79	mU/L			0.27 - 4.20
							B12	494	pmol/L			145 - 639
							FOLATE	35.1	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	2.9	U/L			< 5.0
			V1 (WEEK 0)	1	16NOV2010	12:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	29.7	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	87.5	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	089	5	V1 (WEEK 0)	1	16NOV2010	12:00	PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	3.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	59	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	6.68	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.01	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
			V3 (WEEK 12)	84	07FEB2011	11:30	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	31.5	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	85.7	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	089	5	V3 (WEEK 12)	84	07FEB2011	11:30	TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	42.1	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	28	U/L			< 35
							ALKALINE PHOSPHATASE	77	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	6.92	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.08	mmol/L			0.57 - 2.28
							URIC ACID	262	µmol/L			< 357
			V4 (WEEK 24)	168	02MAY2011	10:15	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	27.4	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	86.6	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	089	5	V4 (WEEK 24)	168	02MAY2011	10:15	SGPT (ALT)	24	U/L			< 35
							ALKALINE PHOSPHATASE	60	U/L			35 - 105
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	6.84	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.83	mmol/L			0.57 - 2.28
							URIC ACID	262	µmol/L			< 357
			V5 (WEEK 36)	252	25JUL2011	12:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	28.7	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	84.9	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	58	U/L			35 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	089	5	V5 (WEEK 36)	252	25JUL2011	12:00	GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	6.79	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.32	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
			V6 (WEEK 52)	364	14NOV2011	12:30	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	31	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	81.3	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	60	U/L			35 - 105
							GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	6.16	mmol/L			< 6.50
							TRIGLYCERIDES	0.95	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	089	5	V6 (WEEK 52)	364	14NOV2011	12:30	URIC ACID	238	µmol/L			< 357
			V7 (WEEK 56)	394	14DEC2011	13:00	SODIUM	143	mmol/L		NCS	135 - 150
							POTASSIUM	4	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	105	mmol/L		NCS	95 - 105
							BICARBONATE	33.1	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.34	mmol/L		NCS	< 8.40
							CREATININE	80.4	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.2	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.3	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	4.17	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	65	g/L		NCS	61.0 - 81.0
							ALBUMIN	43	g/L		NCS	35.0 - 55.0
							SGOT (AST)	16	U/L		NCS	10 - 35
							SGPT (ALT)	14	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	70	U/L		NCS	35 - 105
							GAMMA-GT	9	U/L		NCS	< 40
							CHOLESTEROL	6.29	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	1.5	mmol/L		NCS	0.57 - 2.28
							URIC ACID	226	µmol/L		NCS	< 357
	093	17	SCREENING	-3	29NOV2010	12:30	SODIUM	141	mmol/L			135 - 150

NCS=not clinically significant, CS=clinically significant

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	093	17	SCREENING	-3	29NOV2010	12:30	POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	21.1	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	93.7	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35
							ALKALINE PHOSPHATASE	61	U/L			35 - 105
							GAMMA-GT	31	U/L			< 40
							CHOLESTEROL	7.95	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	4.9	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	404	µmol/L	HIGH	NCS	< 357
							T3	1.26	nmol/L			1.2 - 3.1
							T4	78.7	nmol/L			65.8 - 182
							TSH	1.42	mU/L			0.27 - 4.20
							B12	176	pmol/L			145 - 639

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	093	17	SCREENING	-3	29NOV2010	12:30	FOLATE	30.6	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	2.7	U/L			< 5.0
			V1 (WEEK 0)	1	02DEC2010	8:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	80.4	µmol/L			45.1 - 84.0
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	3.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	61	U/L			35 - 105
							GAMMA-GT	31	U/L			< 40
							CHOLESTEROL	8.73	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.01	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	393	µmol/L	HIGH	NCS	< 357
			V3 (WEEK 12)	86	25FEB2011	11:35	SODIUM	140	mmol/L			135 - 150

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	093	17	V3 (WEEK 12)	86	25FEB2011	11:35	POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	26.3	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	78.7	µmol/L			45.1 - 84.0
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	26	U/L			< 35
							ALKALINE PHOSPHATASE	60	U/L			35 - 105
							GAMMA-GT	38	U/L			< 40
							CHOLESTEROL	8.29	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	4.39	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	381	µmol/L	HIGH	NCS	< 357
			V4 (WEEK 24)	173	23MAY2011	11:45	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	24.9	mmol/L			22.0 - 29.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	093	17	V4 (WEEK 24)	173	23MAY2011	11:45	UREA	6.51	mmol/L			< 8.40
							CREATININE	75.1	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	3.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	44.6	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	63	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	6.27	mmol/L			< 6.50
							TRIGLYCERIDES	0.71	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
			V5 (WEEK 36)	258	16AUG2011	10:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0
							UREA	8.52	mmol/L	HIGH	NCS	< 8.40
							CREATININE	103.4	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	093	17	V5 (WEEK 36)	258	16AUG2011	10:30	PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	7.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	37	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	44	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	71	U/L			35 - 105
							GAMMA-GT	32	U/L			< 40
							CHOLESTEROL	4.79	mmol/L			< 6.50
							TRIGLYCERIDES	2.09	mmol/L			0.57 - 2.28
							URIC ACID	446	µmol/L	HIGH	NCS	< 357
			V6 (WEEK 52)	370	06DEC2011	10:40	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	84	µmol/L			45.1 - 84.0
							CALCIUM	2.1	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	093	17	V6 (WEEK 52)	370	06DEC2011	10:40	TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	59	U/L			35 - 105
							GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	7.87	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.14	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 357
			V7 (WEEK 56)	392	28DEC2011	10:15	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	96.4	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	40.9	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	093	17	V7 (WEEK 56)	392	28DEC2011	10:15	SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	47	U/L			35 - 105
							GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	6.76	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.88	mmol/L			0.57 - 2.28
							URIC ACID	399	µmol/L	HIGH	NCS	< 357
	097	12	SCREENING	-21	27OCT2010	8:30	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	5.3	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	26.6	mmol/L			22.0 - 29.0
							UREA	7.18	mmol/L			< 8.40
							CREATININE	111.4	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	78	g/L			61.0 - 81.0
							ALBUMIN	51	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	42	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	097	12	SCREENING	-21	27OCT2010	8:30	ALKALINE PHOSPHATASE	55	U/L			40 - 130
							GAMMA-GT	34	U/L			< 60
							CHOLESTEROL	5.13	mmol/L			< 6.50
							TRIGLYCERIDES	1.5	mmol/L			0.57 - 2.28
							URIC ACID	345	µmol/L			< 416
							T3	1.76	nmol/L			1.2 - 3.1
							T4	135.5	nmol/L			65.8 - 182
							TSH	0.01	mU/L	LOW	NCS	0.27 - 4.20
							B12	398	pmol/L			145 - 639
							FOLATE	37.6	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	17NOV2010	8:30	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	29.1	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	114	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	097	12	V1 (WEEK 0)	1	17NOV2010	8:30	SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	45	U/L			< 50
							ALKALINE PHOSPHATASE	50	U/L			40 - 130
							GAMMA-GT	38	U/L			< 60
							CHOLESTEROL	5.23	mmol/L			< 6.50
							TRIGLYCERIDES	2.14	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	85	09FEB2011	8:15	URIC ACID	333	µmol/L			< 416
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	28	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	110.5	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	8.4	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	48	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
ACI-91	097	12	V3 (WEEK 12)	85	09FEB2011	8:15	ALKALINE PHOSPHATASE	45	U/L			40 - 130
							GAMMA-GT	38	U/L			< 60
							CHOLESTEROL	5.02	mmol/L			< 6.50
							TRIGLYCERIDES	2.66	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	345	µmol/L			< 416
Placebo	001	1	SCREENING	-7	02APR2009	10:40	SODIUM	149	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	22.4	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	59	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	51	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	85	U/L			35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	001	1	SCREENING	-7	02APR2009	10:40	GAMMA-GT	28	U/L			< 40
							CHOLESTEROL	6.19	mmol/L			< 6.50
							TRIGLYCERIDES	1.56	mmol/L			0.57 - 2.28
							URIC ACID	172	µmol/L			< 357
							T3	1.34	nmol/L			1.2 - 3.1
							T4	141.9	nmol/L			65.8 - 182
							TSH	0.86	mU/L			0.27 - 4.20
							B12	183	pmol/L			145 - 639
							FOLATE	10.4	nmol/L	LOW	NCS	10.4 - 42.4
							BETA-HCG SERUM	2.7	U/L			< 5.0
			V1 (WEEK 0)	1	09APR2009	10:30	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	20.5	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	49.3	g/L		NCS	35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35

NCS=not clinically significant, CS=clinically significant

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	001	1	V1 (WEEK 0)	1	09APR2009	10:30	SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	84	U/L			35 - 105
							GAMMA-GT	27	U/L			< 40
							CHOLESTEROL	5.83	mmol/L			< 6.50
							TRIGLYCERIDES	1.04	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 357
			V3 (WEEK 12)	90	07JUL2009	8:55	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.4	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	74	U/L			35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	001	1	V3 (WEEK 12)	90	07JUL2009	8:55	GAMMA-GT	31	U/L			< 40
							CHOLESTEROL	7.1	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.94	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
			V4 (WEEK 24)	162	17SEP2009	11:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	28.9	mmol/L			22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	62	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE	79	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	35	U/L			< 40
							CHOLESTEROL	5.83	mmol/L			< 6.50
TRIGLYCERIDES	2.13	mmol/L			0.57 - 2.28							

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	001	1	V4 (WEEK 24)	162	17SEP2009	11:00	URIC ACID	280	µmol/L			< 357
			V5 (WEEK 36)	246	10DEC2009	9:10	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.5	mmol/L	LOW	NCS	3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	27.6	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	63	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	89	U/L			35 - 105
							GAMMA-GT	44	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.98	mmol/L			< 6.50
							TRIGLYCERIDES	2.49	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	268	µmol/L			< 357
			V6 (WEEK 52)	365	08APR2010	9:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.5	mmol/L	LOW	NCS	3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	001	1	V6 (WEEK 52)	365	08APR2010	9:00	CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26.1	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	79	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	4.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	48.6	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 35
							SGPT (ALT)	24	U/L			< 35
							ALKALINE	77	U/L			35 - 105
			V7 (WEEK 56)	393	06MAY2010	13:15	PHOSPHATASE					
							GAMMA-GT	46	U/L	HIGH	NCS	< 40
							CHOLESTEROL	5.49	mmol/L			< 6.50
							TRIGLYCERIDES	3.06	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	297	µmol/L			< 357
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.7	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0
							UREA	7.35	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	001	1	V7 (WEEK 56)	393	06MAY2010	13:15	CREATININE	72	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	47.8	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	31	U/L			< 35
							ALKALINE PHOSPHATASE	96	U/L			35 - 105
							GAMMA-GT	58	U/L	HIGH	NCS	< 40
							CHOLESTEROL	6.11	mmol/L			< 6.50
							TRIGLYCERIDES	2.91	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	286	µmol/L			< 357
	003	1	SCREENING	-21	07MAY2009	10:10	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	54	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	003	1	SCREENING	-21	07MAY2009	10:10	PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	47.5	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 35
							SGPT (ALT)	31	U/L			< 35
							ALKALINE PHOSPHATASE	77	U/L			35 - 105
							GAMMA-GT	75	U/L	HIGH	NCS	< 40
							CHOLESTEROL	6.81	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.33	mmol/L			0.57 - 2.28
							URIC ACID	250	µmol/L			< 357
							T3	1.59	nmol/L			1.2 - 3.1
							T4	81.3	nmol/L			65.8 - 182
							TSH	0.86	mU/L			0.27 - 4.20
							B12	289	pmol/L			145 - 639
							FOLATE	26	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1.6	U/L			< 5.0
			V1 (WEEK 0)	1	28MAY2009	11:25	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	27.2	mmol/L			22.0 - 29.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	003	1	V1 (WEEK 0)	1	28MAY2009	11:25	UREA	6.85	mmol/L			< 8.40
							CREATININE	47	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	43.6	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	84	U/L			35 - 105
							GAMMA-GT	37	U/L			< 40
							CHOLESTEROL	6.42	mmol/L			< 6.50
							TRIGLYCERIDES	1.45	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	90	25AUG2009	11:50	URIC ACID	226	µmol/L			< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	24.7	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	59	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	003	1	V3 (WEEK 12)	90	25AUG2009	11:50	PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	20.5	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	46.9	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE PHOSPHATASE	75	U/L			35 - 105
							GAMMA-GT	55	U/L	HIGH	NCS	< 40
							CHOLESTEROL	6.86	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.47	mmol/L			0.57 - 2.28
							URIC ACID	297	µmol/L			< 357
			V4 (WEEK 24)	169	12NOV2009	10:15	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	25.4	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	58	µmol/L			< 97
							CALCIUM	2.9	mmol/L	HIGH	NCS	2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	6	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	003	1	V4 (WEEK 24)	169	12NOV2009	10:15	TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	46.2	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	79	U/L			35 - 105
							GAMMA-GT	30	U/L			< 40
							CHOLESTEROL	5.83	mmol/L			< 6.50
							TRIGLYCERIDES	1.12	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 357
	005	2	SCREENING	-16	19MAY2009	14:00	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	22.5	mmol/L			22.0 - 29.0
							UREA	7.01	mmol/L			< 8.40
							CREATININE	67	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.5	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	43.1	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	005	2	SCREENING	-16	19MAY2009	14:00	SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	91	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	5.83	mmol/L			< 6.50
							TRIGLYCERIDES	3.44	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	286	µmol/L			< 357
							T3	1.26	nmol/L			1.2 - 3.1
							T4	80	nmol/L			65.8 - 182
							TSH	2.26	mU/L			0.27 - 4.20
							B12	238	pmol/L			145 - 639
							FOLATE	13.8	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	2.6	U/L			< 5.0
			V1 (WEEK 0)	1	04JUN2009	8:45	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	23.1	mmol/L			22.0 - 29.0
							UREA	7.52	mmol/L			< 8.40
							CREATININE	52	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.5	mmol/L			0.8 - 1.6
							GLUCOSE	6	mmol/L	HIGH	NCS	2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	005	2	V1 (WEEK 0)	1	04JUN2009	8:45	TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	39	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	83	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
			V3 (WEEK 12)	83	25AUG2009	8:30	CHOLESTEROL	5.8	mmol/L			< 6.50
							TRIGLYCERIDES	1.46	mmol/L			0.57 - 2.28
							URIC ACID	214	µmol/L			< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	24.5	mmol/L			22.0 - 29.0
							UREA	6.85	mmol/L			< 8.40
							CREATININE	53	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	43.1	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	005	2	V3 (WEEK 12)	83	25AUG2009	8:30	SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	76	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	5.85	mmol/L			< 6.50
							TRIGLYCERIDES	1.44	mmol/L			0.57 - 2.28
			V4 (WEEK 24)	168	18NOV2009	10:00	URIC ACID	250	µmol/L			< 357
							SODIUM	147	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	57	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	005	2	V4 (WEEK 24)	168	18NOV2009	10:00	ALKALINE PHOSPHATASE	85	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	4.9	mmol/L			< 6.50
							TRIGLYCERIDES	2.07	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	258	16FEB2010	9:00	URIC ACID	250	µmol/L			< 357
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	28.9	mmol/L			22.0 - 29.0
							UREA	8.68	mmol/L	HIGH	NCS	< 8.40
							CREATININE	65	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	40	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	70	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	005	2	V5 (WEEK 36)	258	16FEB2010	9:00	CHOLESTEROL	5.31	mmol/L			< 6.50
							TRIGLYCERIDES	1.54	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
			V6 (WEEK 52)	364	02JUN2010	9:00	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	22	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	66	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	3.78	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	75	U/L			35 - 105
							GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	4.79	mmol/L			< 6.50
							TRIGLYCERIDES	2.6	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	226	µmol/L			< 357

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	005	2	V7 (WEEK 56)	400	08JUL2010	9:15	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.7	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	57	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	39.3	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	70	U/L			35 - 105
							GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	4.35	mmol/L			< 6.50
							TRIGLYCERIDES	1.61	mmol/L			0.57 - 2.28
							URIC ACID	250	µmol/L			< 357
	009	1	SCREENING	-33	06AUG2009	11:45	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	009	1	SCREENING	-33	06AUG2009	11:45	CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	56	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	44.5	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE	73	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	34	U/L			< 40
							CHOLESTEROL	5.57	mmol/L			< 6.50
							TRIGLYCERIDES	0.82	mmol/L			0.57 - 2.28
							URIC ACID	202	µmol/L			< 357
							T3	1.39	nmol/L			1.2 - 3.1
							T4	94.2	nmol/L			65.8 - 182
							TSH	0.1	mU/L	LOW	NCS	0.27 - 4.20
							B12	369	pmol/L			145 - 639
							FOLATE	37.4	nmol/L			10.4 - 42.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	009	1	SCREENING V1 (WEEK 0)	-33 1	06AUG2009	11:45	BETA-HCG SERUM	1.3	U/L			< 5.0
					08SEP2009	9:10	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	20	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	3.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45.9	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	76	U/L			35 - 105
							GAMMA-GT	38	U/L			< 40
							CHOLESTEROL	6.01	mmol/L			< 6.50
							TRIGLYCERIDES	0.63	mmol/L			0.57 - 2.28
							URIC ACID	220	µmol/L			< 357
			V3 (WEEK 12)	94	10DEC2009	9:40	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	009	1	V3 (WEEK 12)	94	10DEC2009	9:40	CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	57	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	2	mmol/L	LOW	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	46.3	g/L			35.0 - 55.0
							SGOT (AST)	42	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	56	U/L	HIGH	NCS	< 35
							ALKALINE	82	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	46	U/L	HIGH	NCS	< 40
							CHOLESTEROL	6.35	mmol/L			< 6.50
							TRIGLYCERIDES	0.89	mmol/L			0.57 - 2.28
							URIC ACID	167	µmol/L			< 357
			V4 (WEEK 24)	178	04MAR2010	12:50	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	22.3	mmol/L			22.0 - 29.0
							UREA	3.34	mmol/L			< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	009	1	V4 (WEEK 24)	178	04MAR2010	12:50	CREATININE	79	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	19.24	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	48.4	g/L			35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35
							ALKALINE PHOSPHATASE	73	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	6.09	mmol/L			< 6.50
							TRIGLYCERIDES	0.88	mmol/L			0.57 - 2.28
							URIC ACID	155	µmol/L			< 357
			V5 (WEEK 36)	246	11MAY2010	10:20	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	19.8	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	68	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	009	1	V5 (WEEK 36)	246	11MAY2010	10:20	GLUCOSE	4.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	16	U/L			10 - 35
							SGPT (ALT)	11	U/L			< 35
							ALKALINE PHOSPHATASE	59	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	5.93	mmol/L			< 6.50
							TRIGLYCERIDES	0.7	mmol/L			0.57 - 2.28
							URIC ACID	184	µmol/L			< 357
		V6 (WEEK 52)		361	03SEP2010	10:15	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	20.8	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	67	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	13.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	1.7	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	009	1	V6 (WEEK 52)	361	03SEP2010	10:15	ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	15	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	59	U/L			35 - 105
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	6.27	mmol/L			< 6.50
							TRIGLYCERIDES	0.73	mmol/L			0.57 - 2.28
							URIC ACID	196	µmol/L			< 357
			V7 (WEEK 56)	389	01OCT2010	9:15	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	22	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	69	µmol/L			58.3 - 96.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	9.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	1.7	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	009	1	V7 (WEEK 56)	389	01OCT2010	9:15	ALKALINE PHOSPHATASE	55	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	5.59	mmol/L			< 6.50
							TRIGLYCERIDES	0.98	mmol/L			0.57 - 2.28
							URIC ACID	196	µmol/L			< 357
	011	1	SCREENING	-21	05NOV2009	13:10	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	27	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	48	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	73	U/L			35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	011	1	SCREENING	-21	05NOV2009	13:10	GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.55	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.97	mmol/L			0.57 - 2.28
							URIC ACID	232	µmol/L			< 357
							T3	1.22	nmol/L	LOW	NCS	1.2 - 3.1
							T4	120	nmol/L			65.8 - 182
							TSH	0.01	mU/L	LOW	NCS	0.27 - 4.20
							B12	291	pmol/L			145 - 639
							FOLATE	16.5	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	26NOV2009	10:25	BETA-HCG SERUM	1	U/L			< 5.0
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	94	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	27.1	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	51	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	7.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	80	g/L			61.0 - 81.0
							ALBUMIN	48.9	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	011	1	V1 (WEEK 0)	1	26NOV2009	10:25	SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	84	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	6.76	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.03	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
			V3 (WEEK 12)	85	18FEB2010	9:05	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	28.9	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	64	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	6.45	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	56	U/L			35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	011	1	V3 (WEEK 12)	85	18FEB2010	9:05	GAMMA-GT	12	U/L			< 40
			V4 (WEEK 24)	162	06MAY2010	13:30	CHOLESTEROL	6.19	mmol/L			< 6.50
							TRIGLYCERIDES	0.58	mmol/L			0.57 - 2.28
							URIC ACID	214	µmol/L			< 357
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	23.2	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	52	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	49.5	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	66	U/L			35 - 105
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	6.68	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.75	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	011	1	V4 (WEEK 24)	162	06MAY2010	13:30	URIC ACID	226	µmol/L			< 357
			V5 (WEEK 36)	253	05AUG2010	12:10	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	19.7	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	56	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.17	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	63	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.63	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.84	mmol/L			0.57 - 2.28
							URIC ACID	232	µmol/L			< 357
			V6 (WEEK 52)	366	26NOV2010	10:10	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	011	1	V6 (WEEK 52)	366	26NOV2010	10:10	CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	23.5	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	56.6	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	10	U/L			< 35
							ALKALINE	63	U/L			35 - 105
			V7 (WEEK 56)	397	27DEC2010	12:30	PHOSPHATASE					
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	6.84	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.86	mmol/L			0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	23.2	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	011	1	V7 (WEEK 56)	397	27DEC2010	12:30	CREATININE	62.8	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 35
							SGPT (ALT)	11	U/L			< 35
							ALKALINE	59	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	6.03	mmol/L			< 6.50
							TRIGLYCERIDES	0.82	mmol/L			0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
	013	4	SCREENING	-30	17AUG2009	10:00	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	7.01	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	013	4	SCREENING	-30	17AUG2009	10:00	PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	45.5	g/L			35.0 - 55.0
							SGOT (AST)	31	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	73	U/L			35 - 105
							GAMMA-GT	30	U/L			< 40
							CHOLESTEROL	5.08	mmol/L			< 6.50
							TRIGLYCERIDES	1.63	mmol/L			0.57 - 2.28
							URIC ACID	238	µmol/L			< 357
							T3	1.49	nmol/L			1.2 - 3.1
							T4	91.6	nmol/L			65.8 - 182
							TSH	0.54	mU/L			0.27 - 4.20
							B12	230	pmol/L			145 - 639
							FOLATE	16.5	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1	U/L			< 5.0
			V1 (WEEK 0)	1	16SEP2009	9:00	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	013	4	V1 (WEEK 0)	1	16SEP2009	9:00	UREA	7.18	mmol/L			< 8.40
							CREATININE	59	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	35	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	63	U/L			35 - 105
							GAMMA-GT	24	U/L			< 40
							CHOLESTEROL	4.71	mmol/L			< 6.50
							TRIGLYCERIDES	1.58	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 357
			V3 (WEEK 12)	85	09DEC2009	10:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	24.5	mmol/L			22.0 - 29.0
							UREA	7.01	mmol/L			< 8.40
							CREATININE	59	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	013	4	V3 (WEEK 12)	85	09DEC2009	10:00	PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	3.61	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 35
							SGPT (ALT)	27	U/L			< 35
							ALKALINE PHOSPHATASE	70	U/L			35 - 105
							GAMMA-GT	22	U/L			< 40
							CHOLESTEROL	4.48	mmol/L			< 6.50
							TRIGLYCERIDES	0.87	mmol/L			0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
			V4 (WEEK 24)	170	04MAR2010	10:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	73	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	013	4	V4 (WEEK 24)	170	04MAR2010	10:00	TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	46.3	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	24	U/L			< 35
							ALKALINE PHOSPHATASE	62	U/L			35 - 105
							GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	4.48	mmol/L			< 6.50
							TRIGLYCERIDES	1.13	mmol/L			0.57 - 2.28
							URIC ACID	214	µmol/L			< 357
			V5 (WEEK 36)	247	20MAY2010	10:25	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	23.5	mmol/L			22.0 - 29.0
							UREA	7.68	mmol/L			< 8.40
							CREATININE	78	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	42.4	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	013	4	V5 (WEEK 36)	247	20MAY2010	10:25	SGPT (ALT)	22	U/L			< 35
							ALKALINE PHOSPHATASE	62	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	4.79	mmol/L			< 6.50
							TRIGLYCERIDES	1.62	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 357
			V6 (WEEK 52)	366	16SEP2010	11:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	27.5	mmol/L			22.0 - 29.0
							UREA	6.85	mmol/L			< 8.40
							CREATININE	70	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE PHOSPHATASE	58	U/L			35 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	013	4	V6 (WEEK 52)	366	16SEP2010	11:00	GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	5.05	mmol/L			< 6.50
							TRIGLYCERIDES	1.33	mmol/L			0.57 - 2.28
							URIC ACID	220	µmol/L			< 357
			V7 (WEEK 56)	400	20OCT2010	11:45	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25.7	mmol/L			22.0 - 29.0
							UREA	7.35	mmol/L			< 8.40
							CREATININE	69	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35
							ALKALINE PHOSPHATASE	62	U/L			35 - 105
							GAMMA-GT	21	U/L			< 40
							CHOLESTEROL	4.77	mmol/L			< 6.50
							TRIGLYCERIDES	1.31	mmol/L			0.57 - 2.28

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	013	4	V7 (WEEK 56)	400	20OCT2010	11:45	URIC ACID	226	µmol/L			< 357
	016	4	SCREENING	-28	01FEB2010	10:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	26	mmol/L			22.0 - 29.0
							UREA	3.01	mmol/L			< 8.40
							CREATININE	95	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 50
							SGPT (ALT)	25	U/L			< 50
							ALKALINE PHOSPHATASE	104	U/L			40 - 130
							GAMMA-GT	29	U/L			< 60
							CHOLESTEROL	6.79	mmol/L	HIGH	CS	< 6.50
							TRIGLYCERIDES	2.04	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 416
							T3	1.54	nmol/L			1.2 - 3.1

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	016	4	SCREENING	-28	01FEB2010	10:00	T4	116.1	nmol/L			65.8 - 182
							TSH	1.61	mU/L			0.27 - 4.20
							B12	258	pmol/L			145 - 639
			V1 (WEEK 0)	1	01MAR2010	10:00	FOLATE	37.6	nmol/L			10.4 - 42.4
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	100	µmol/L			< 106
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE	97	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	22	U/L			< 60
							CHOLESTEROL	6.97	mmol/L	HIGH	CS	< 6.50
							TRIGLYCERIDES	1.84	mmol/L			0.57 - 2.28

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	016	4	V1 (WEEK 0)	1	01MAR2010	10:00	URIC ACID	351	µmol/L			< 416
			V3 (WEEK 12)	80	19MAY2010	9:15	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	22.5	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	98	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE PHOSPHATASE	90	U/L			40 - 130
							GAMMA-GT	29	U/L			< 60
							CHOLESTEROL	6.37	mmol/L			< 6.50
							TRIGLYCERIDES	3.09	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	339	µmol/L			< 416
			V4 (WEEK 24)	162	09AUG2010	10:20	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	016	4	V4 (WEEK 24)	162	09AUG2010	10:20	CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	3.01	mmol/L			< 8.40
							CREATININE	97	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE	91	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	7.2	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.48	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	333	µmol/L			< 416
			V5 (WEEK 36)	253	08NOV2010	9:45	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25.9	mmol/L			22.0 - 29.0
							UREA	3.34	mmol/L			< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	016	4	V5 (WEEK 36)	253	08NOV2010	9:45	CREATININE	92.8	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 50
							SGPT (ALT)	18	U/L			< 50
							ALKALINE PHOSPHATASE	92	U/L			40 - 130
							GAMMA-GT	27	U/L			< 60
							CHOLESTEROL	8	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.99	mmol/L	HIGH	NCS	0.57 - 2.28
			V6 (WEEK 52)	365	28FEB2011	10:30	URIC ACID	345	µmol/L			< 416
							SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	98.1	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range		
					Date	Time								
Placebo	016	4	V6 (WEEK 52)	365	28FEB2011	10:30	GLUCOSE	5.78	mmol/L	HIGH	NCS	2.78 - 5.55		
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0		
							TOTAL PROTEIN	68	g/L			61.0 - 81.0		
							ALBUMIN	45	g/L			35.0 - 55.0		
							SGOT (AST)	27	U/L			10 - 50		
							SGPT (ALT)	30	U/L			< 50		
							ALKALINE	109	U/L			40 - 130		
							PHOSPHATASE							
							GAMMA-GT	39	U/L			< 60		
							CHOLESTEROL	8.16	mmol/L			HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.02	mmol/L			HIGH	NCS	0.57 - 2.28
			V7 (WEEK 56)	403	07APR2011	11:00	URIC ACID	351	µmol/L			< 416		
							SODIUM	141	mmol/L			135 - 150		
							POTASSIUM	4.3	mmol/L			3.6 - 5.4		
							CHLORIDE	100	mmol/L			95 - 105		
							BICARBONATE	23.4	mmol/L			22.0 - 29.0		
							UREA	3.67	mmol/L			< 8.40		
							CREATININE	103.4	µmol/L			59.2 - 103.4		
							CALCIUM	2.5	mmol/L			2.1 - 2.7		
							PHOSPHATE	1	mmol/L			0.8 - 1.6		
							GLUCOSE	6.12	mmol/L	HIGH	NCS	2.78 - 5.55		
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0		
TOTAL PROTEIN	73	g/L	61.0 - 81.0											

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	016	4	V7 (WEEK 56)	403	07APR2011	11:00	ALBUMIN	44.7	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	24	U/L			< 50
							ALKALINE PHOSPHATASE	100	U/L			40 - 130
							GAMMA-GT	32	U/L			< 60
							CHOLESTEROL	8.73	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.65	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	363	µmol/L			< 416
	018	5	SCREENING	-20	03NOV2009	13:15	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.8	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	63	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	82	g/L	HIGH	NCS	61.0 - 81.0
							ALBUMIN	51	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	018	5	SCREENING	-20	03NOV2009	13:15	SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	100	U/L			35 - 105
							GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	4.58	mmol/L			< 6.50
							TRIGLYCERIDES	1.52	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
							T3	1.39	nmol/L			1.2 - 3.1
							T4	91.6	nmol/L			65.8 - 182
							TSH	2.79	mU/L			0.27 - 4.20
							B12	429	pmol/L			145 - 639
							FOLATE	17	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	2.4	U/L			< 5.0
			V1 (WEEK 0)	1	23NOV2009	13:00	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	5.2	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	24.4	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	65	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.62	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	018	5	V1 (WEEK 0)	1	23NOV2009	13:00	TOTAL PROTEIN	79	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	90	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	4.71	mmol/L			< 6.50
			V3 (WEEK 12)	86	16FEB2010	12:45	TRIGLYCERIDES	0.93	mmol/L			0.57 - 2.28
							URIC ACID	220	µmol/L			< 357
							SODIUM	147	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							BICARBONATE	31.1	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	73	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35
							SGPT (ALT)	31	U/L			< 35
							ALKALINE PHOSPHATASE	80	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	018	5	V3 (WEEK 12)	86	16FEB2010	12:45	CHOLESTEROL	4.64	mmol/L			< 6.50
							URIC ACID	262	µmol/L			< 357
			V4 (WEEK 24)	170	11MAY2010	9:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	24.5	mmol/L			22.0 - 29.0
							UREA	7.18	mmol/L			< 8.40
							CREATININE	69	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE PHOSPHATASE	76	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	4.58	mmol/L			< 6.50
							TRIGLYCERIDES	2.12	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 357
			V5 (WEEK 36)	247	27JUL2010	9:00	SODIUM	146	mmol/L			135 - 150

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	018	5	V5 (WEEK 36)	247	27JUL2010	9:00	POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	29.3	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	71	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE	75	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	4.61	mmol/L			< 6.50
							TRIGLYCERIDES	1.54	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 357
			V6 (WEEK 52)	366	23NOV2010	9:20	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25.8	mmol/L			22.0 - 29.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	018	5	V6 (WEEK 52)	366	23NOV2010	9:20	UREA	7.01	mmol/L			< 8.40
							CREATININE	87.5	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35
							ALKALINE PHOSPHATASE	72	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	4.61	mmol/L			< 6.50
							TRIGLYCERIDES	1.7	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	387	14DEC2010	8:50	URIC ACID	268	µmol/L			< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	29.5	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	76	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	018	5	V7 (WEEK 56)	387	14DEC2010	8:50	PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.78	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	26	U/L			< 35
							ALKALINE PHOSPHATASE	72	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	4.69	mmol/L			< 6.50
							TRIGLYCERIDES	1.86	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
	020	5	SCREENING	-26	27JAN2010	15:30	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	31.4	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	69	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	3.89	mmol/L			2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	020	5	SCREENING	-26	27JAN2010	15:30	TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	38	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50
							ALKALINE PHOSPHATASE	51	U/L			40 - 130
							GAMMA-GT	18	U/L			< 60
							CHOLESTEROL	3.06	mmol/L			< 6.50
							TRIGLYCERIDES	0.59	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 416
							T3	1.34	nmol/L			1.2 - 3.1
							T4	68.4	nmol/L			65.8 - 182
							TSH	1.31	mU/L			0.27 - 4.20
							B12	370	pmol/L			145 - 639
			V1 (WEEK 0)	1	22FEB2010	13:20	FOLATE	32.2	nmol/L			10.4 - 42.4
							SODIUM	153	mmol/L	HIGH	NCS	135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	30.9	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	77	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	020	5	V1 (WEEK 0)	1	22FEB2010	13:20	PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	3.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 50
							SGPT (ALT)	31	U/L			< 50
							ALKALINE PHOSPHATASE	50	U/L			40 - 130
							GAMMA-GT	17	U/L			< 60
							CHOLESTEROL	3.06	mmol/L			< 6.50
							TRIGLYCERIDES	0.59	mmol/L			0.57 - 2.28
							URIC ACID	202	µmol/L			< 416
	024	4	SCREENING	-31	16JUL2010	9:30	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	27.7	mmol/L			22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	65	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	024	4	SCREENING	-31	16JUL2010	9:30	TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	15	U/L			< 50
							ALKALINE	75	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	19	U/L			< 60
							CHOLESTEROL	5.8	mmol/L			< 6.50
							TRIGLYCERIDES	1.82	mmol/L			0.57 - 2.28
							URIC ACID	339	µmol/L			< 416
							T3	1.37	nmol/L			1.2 - 3.1
							T4	104.5	nmol/L			65.8 - 182
							TSH	0.95	mU/L			0.27 - 4.20
							B12	328	pmol/L			145 - 639
							FOLATE	10.9	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	16AUG2010	9:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	69	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	024	4	V1 (WEEK 0)	1	16AUG2010	9:30	PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L		2.78 - 5.55	
							TOTAL BILIRUBIN	1.7	µmol/L		< 17.0	
							TOTAL PROTEIN	66	g/L		61.0 - 81.0	
							ALBUMIN	44	g/L		35.0 - 55.0	
							SGOT (AST)	21	U/L		10 - 50	
							SGPT (ALT)	15	U/L		< 50	
							ALKALINE PHOSPHATASE	78	U/L		40 - 130	
							GAMMA-GT	20	U/L		< 60	
							CHOLESTEROL	5.88	mmol/L		< 6.50	
							TRIGLYCERIDES	1.93	mmol/L		0.57 - 2.28	
			V3 (WEEK 12)	87	10NOV2010	10:20	URIC ACID	351	µmol/L		< 416	
							SODIUM	143	mmol/L		135 - 150	
							POTASSIUM	4.4	mmol/L		3.6 - 5.4	
							CHLORIDE	103	mmol/L		95 - 105	
							BICARBONATE	27.4	mmol/L		22.0 - 29.0	
							UREA	4.51	mmol/L		< 8.40	
							CREATININE	69	µmol/L		59.2 - 103.4	
							CALCIUM	2.4	mmol/L		2.1 - 2.7	
							PHOSPHATE	1	mmol/L		0.8 - 1.6	
							GLUCOSE	5.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L		< 17.0	

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	024	4	V3 (WEEK 12)	87	10NOV2010	10:20	TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50
							ALKALINE PHOSPHATASE	93	U/L			40 - 130
							GAMMA-GT	23	U/L			< 60
							CHOLESTEROL	6.66	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.81	mmol/L			0.57 - 2.28
							URIC ACID	387	µmol/L			< 416
			V4 (WEEK 24)	171	02FEB2011	9:30	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	26.4	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	69.8	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	31	U/L			10 - 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	024	4	V4 (WEEK 24)	171	02FEB2011	9:30	SGPT (ALT)	25	U/L			< 50
							ALKALINE PHOSPHATASE	88	U/L			40 - 130
							GAMMA-GT	22	U/L			< 60
							CHOLESTEROL	6.86	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.22	mmol/L			0.57 - 2.28
							URIC ACID	416	µmol/L	HIGH	NCS	< 416
			V5 (WEEK 36)	246	18APR2011	10:00	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	24.8	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	76	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	6.39	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	44.7	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	27	U/L			< 50
							ALKALINE PHOSPHATASE	101	U/L			40 - 130

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	024	4	V5 (WEEK 36)	246	18APR2011	10:00	GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	5.78	mmol/L			< 6.50
							TRIGLYCERIDES	2.62	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	387	µmol/L			< 416
			V6 (WEEK 52)	358	08AUG2011	9:30	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	108	mmol/L	HIGH		95 - 105
							BICARBONATE	26.8	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	84.9	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	46.6	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	23	U/L			< 50
							ALKALINE PHOSPHATASE	98	U/L			40 - 130
							GAMMA-GT	27	U/L			< 60
							CHOLESTEROL	6.22	mmol/L			< 6.50
							TRIGLYCERIDES	2.79	mmol/L	HIGH		0.57 - 2.28

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	024	4	V6 (WEEK 52)	358	08AUG2011	9:30	URIC ACID	434	µmol/L	HIGH		< 416
			V7 (WEEK 56)	393	12SEP2011	11:40	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	83.1	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	44.9	g/L			35.0 - 55.0
							SGOT (AST)	37	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE PHOSPHATASE	93	U/L			40 - 130
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	7.61	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.88	mmol/L			0.57 - 2.28
							URIC ACID	452	µmol/L	HIGH	NCS	< 416
	028	20	SCREENING	-8	18NOV2010	10:20	SODIUM	140	mmol/L			135 - 150

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	028	20	SCREENING	-8	18NOV2010	10:20	POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	25.8	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	76	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE	99	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	7.98	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.12	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
							T3	1.29	nmol/L			1.2 - 3.1
							T4	85.1	nmol/L			65.8 - 182
							TSH	1.82	mU/L			0.27 - 4.20
							B12	540	pmol/L			145 - 639

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	028	20	SCREENING	-8	18NOV2010	10:20	FOLATE	45.3	nmol/L	HIGH	NCS	10.4 - 42.4
							BETA-HCG SERUM	2.1	U/L			< 5.0
			V1 (WEEK 0)	1	26NOV2010	9:15	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	22.7	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	73.4	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	94	U/L			35 - 105
							GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	7.43	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.38	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
			V3 (WEEK 12)	89	22FEB2011	10:20	SODIUM	140	mmol/L			135 - 150

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	028	20	V3 (WEEK 12)	89	22FEB2011	10:20	POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	26.8	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	79.6	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
			V4 (WEEK 24)	180	24MAY2011	10:05	ALKALINE	113	U/L	HIGH	NCS	35 - 105
							PHOSPHATASE					
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	7.67	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	4.07	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	256	µmol/L			< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	028	20	V4 (WEEK 24)	180	24MAY2011	10:05	UREA	4.18	mmol/L			< 8.40
							CREATININE	69.8	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	41.2	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	105	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	6.99	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.52	mmol/L	HIGH	NCS	0.57 - 2.28
			V5 (WEEK 36)	273	25AUG2011	10:45	URIC ACID	256	µmol/L			< 357
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	82.2	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	028	20	V5 (WEEK 36)	273	25AUG2011	10:45	PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	100	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	7.17	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.6	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
			V6 (WEEK 52)	364	24NOV2011	8:09	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	24.7	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	75.1	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	028	20	V6 (WEEK 52)	364	24NOV2011	8:09	TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	97	U/L			35 - 105
							GAMMA-GT	18	U/L			< 40
							CHOLESTEROL	7.8	mmol/L	HIGH	NCS	< 6.50
			V7 (WEEK 56)	390	20DEC2011	10:15	TRIGLYCERIDES	2.74	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	274	µmol/L			< 357
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	79.6	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48.9	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	028	20	V7 (WEEK 56)	390	20DEC2011	10:15	SGPT (ALT)	20	U/L			< 35
							ALKALINE PHOSPHATASE	105	U/L			35 - 105
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	7.43	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2	mmol/L			0.57 - 2.28
							URIC ACID	268	µmol/L			< 357
	029	8	SCREENING	-3	26JAN2010	9:45	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	28.4	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	75	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	7.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	47.2	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	22	U/L			< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	029	8	SCREENING	-3	26JAN2010	9:45	ALKALINE PHOSPHATASE	74	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	4.45	mmol/L			< 6.50
							TRIGLYCERIDES	3.17	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	167	µmol/L			< 357
							T3	1.56	nmol/L			1.2 - 3.1
							T4	162.5	nmol/L			65.8 - 182
							TSH	0.32	mU/L			0.27 - 4.20
							B12	261	pmol/L			145 - 639
							FOLATE	29.7	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	3.1	U/L			< 5.0
		V1 (WEEK 0)		1	29JAN2010	10:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	29.1	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	89	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	7.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	029	8	V1 (WEEK 0)	1	29JAN2010	10:00	ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 35
							SGPT (ALT)	27	U/L			< 35
							ALKALINE PHOSPHATASE	75	U/L			35 - 105
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	4.33	mmol/L			< 6.50
							TRIGLYCERIDES	3.31	mmol/L	HIGH	NCS	0.57 - 2.28
			V3 (WEEK 12)	82	20APR2010	11:50	URIC ACID	190	µmol/L			< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	20.7	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	74	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	7.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	029	8	V3 (WEEK 12)	82	20APR2010	11:50	ALKALINE PHOSPHATASE	73	U/L			35 - 105
			V4 (WEEK 24)	158	05JUL2010	11:10	GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	4.22	mmol/L			< 6.50
							TRIGLYCERIDES	3.59	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	155	µmol/L			< 357
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	23.9	mmol/L			22.0 - 29.0
							UREA	7.18	mmol/L			< 8.40
							CREATININE	84	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	8.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	60	g/L	LOW	NCS	61.0 - 81.0
							ALBUMIN	44.4	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	76	U/L			35 - 105
							GAMMA-GT	16	U/L			< 40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	029	8	V4 (WEEK 24)	158	05JUL2010	11:10	CHOLESTEROL	4.38	mmol/L			< 6.50
							TRIGLYCERIDES	3.02	mmol/L	HIGH	NCS	0.57 - 2.28
			V5 (WEEK 36)	245	30SEP2010	11:25	URIC ACID	184	µmol/L			< 357
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	23.2	mmol/L			22.0 - 29.0
							UREA	6.85	mmol/L			< 8.40
							CREATININE	91.1	µmol/L			58.3 - 96.4
							CALCIUM	2.1	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	6.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	84	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	4.56	mmol/L			< 6.50
							TRIGLYCERIDES	2.75	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	172	µmol/L			< 357

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	029	8	V6 (WEEK 52)	369	01FEB2011	11:45	SODIUM	147	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	28.7	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	89.3	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	7.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	45.7	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	96	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	5.08	mmol/L			< 6.50
							TRIGLYCERIDES	4.71	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	172	µmol/L			< 357
			V7 (WEEK 56)	391	23FEB2011	11:05	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	029	8	V7 (WEEK 56)	391	23FEB2011	11:05	BICARBONATE	26.6	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	93.7	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	7.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0
							ALBUMIN	43.6	g/L			35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE	84	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	4.84	mmol/L			< 6.50
							TRIGLYCERIDES	3.72	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	202	µmol/L			< 357
	031	8	SCREENING	-14	06MAY2010	13:15	SODIUM	137	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	031	8	SCREENING	-14	06MAY2010	13:15	CREATININE	76	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	51	g/L			35.0 - 55.0
							SGOT (AST)	37	U/L			10 - 50
							SGPT (ALT)	36	U/L			< 50
							ALKALINE	114	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	5.91	mmol/L			< 6.50
							TRIGLYCERIDES	0.82	mmol/L			0.57 - 2.28
							URIC ACID	250	µmol/L			< 416
							T3	1.62	nmol/L			1.2 - 3.1
							T4	104.5	nmol/L			65.8 - 182
							TSH	0.44	mU/L			0.27 - 4.20
							B12	348	pmol/L			145 - 639
							FOLATE	13.8	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	20MAY2010	10:00	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	031	8	V1 (WEEK 0)	1	20MAY2010	10:00	BICARBONATE	23.5	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	92	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	48.2	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 50
							SGPT (ALT)	32	U/L			< 50
							ALKALINE	105	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	25	U/L			< 60
							CHOLESTEROL	6.11	mmol/L			< 6.50
							TRIGLYCERIDES	0.9	mmol/L			0.57 - 2.28
							URIC ACID	274	µmol/L			< 416
			V3 (WEEK 12)	90	17AUG2010	10:45	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	5.2	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26.9	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	85	µmol/L			< 106

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	031	8	V3 (WEEK 12)	90	17AUG2010	10:45	CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	49.1	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	23	U/L			< 50
							ALKALINE PHOSPHATASE	120	U/L			40 - 130
							GAMMA-GT	20	U/L			< 60
							CHOLESTEROL	5.88	mmol/L			< 6.50
							TRIGLYCERIDES	1	mmol/L			0.57 - 2.28
							URIC ACID	256	µmol/L			< 416
			V4 (WEEK 24)	174	09NOV2010	11:35	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	87.5	µmol/L			59.2 - 103.4
							CALCIUM	2.8	mmol/L	HIGH	NCS	2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	031	8	V4 (WEEK 24)	174	09NOV2010	11:35	TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	81	g/L			61.0 - 81.0
							ALBUMIN	57	g/L	HIGH	NCS	35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE	129	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	23	U/L			< 60
							CHOLESTEROL	6.19	mmol/L			< 6.50
							TRIGLYCERIDES	0.73	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	251	25JAN2011	12:00	URIC ACID	262	µmol/L			< 416
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	84	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	7.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	031	8	V5 (WEEK 36)	251	25JAN2011	12:00	SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	24	U/L			< 50
							ALKALINE PHOSPHATASE	102	U/L			40 - 130
							GAMMA-GT	18	U/L			< 60
							CHOLESTEROL	5.46	mmol/L			< 6.50
							TRIGLYCERIDES	1.36	mmol/L			0.57 - 2.28
							URIC ACID	268	µmol/L			< 416
			V6 (WEEK 52)	363	17MAY2011	11:40	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	24.7	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	91.9	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	031	8	V6 (WEEK 52)	363	17MAY2011	11:40	ALKALINE PHOSPHATASE	134	U/L	HIGH	NCS	40 - 130
							GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	5.85	mmol/L			< 6.50
							TRIGLYCERIDES	1.12	mmol/L			0.57 - 2.28
							URIC ACID	286	µmol/L			< 416
			V7 (WEEK 56)	391	14JUN2011	10:14	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	5.5	mmol/L	HIGH	NCS	3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	26.3	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	85.7	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	26	U/L			< 50
							ALKALINE PHOSPHATASE	119	U/L			40 - 130
							GAMMA-GT	21	U/L			< 60

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	031	8	V7 (WEEK 56)	391	14JUN2011	10:14	CHOLESTEROL	5.15	mmol/L			< 6.50
							TRIGLYCERIDES	1.14	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 416
	034	9	SCREENING	-22	24FEB2010	8:50	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	22.3	mmol/L			22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	73	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	7.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE	74	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	6.35	mmol/L			< 6.50
							TRIGLYCERIDES	1.53	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	034	9	SCREENING	-22	24FEB2010	8:50	URIC ACID	232	µmol/L			< 357
							T3	1.25	nmol/L			1.2 - 3.1
							T4	123.8	nmol/L			65.8 - 182
							TSH	1.67	mU/L			0.27 - 4.20
							B12	205	pmol/L			145 - 639
							FOLATE	14.9	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	3.9	U/L			< 5.0
			V1 (WEEK 0)	1	18MAR2010	8:50	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	73	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.6	mmol/L	LOW	NCS	0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	46.4	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE	62	U/L			35 - 105
							PHOSPHATASE					

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	034	9	V1 (WEEK 0)	1	18MAR2010	8:50	GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	5.83	mmol/L			< 6.50
							TRIGLYCERIDES	1.23	mmol/L			0.57 - 2.28
							URIC ACID	232	µmol/L			< 357
			V3 (WEEK 12)	83	08JUN2010	9:10	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	23	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	75	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	7.01	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	69	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	5.83	mmol/L			< 6.50
							TRIGLYCERIDES	1.14	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	034	9	V3 (WEEK 12)	83	08JUN2010	9:10	URIC ACID	232	µmol/L			< 357
			V4 (WEEK 24)	175	08SEP2010	8:40	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	3.5	mmol/L	LOW	NCS	3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	26.7	mmol/L			22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	69	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	7.45	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	18	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	71	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	6.27	mmol/L			< 6.50
							TRIGLYCERIDES	1.04	mmol/L			0.57 - 2.28
							URIC ACID	232	µmol/L			< 357
			V5 (WEEK 36)	258	30NOV2010	8:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	034	9	V5 (WEEK 36)	258	30NOV2010	8:00	CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.8	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	70.7	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	6.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	46.7	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE	75	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.35	mmol/L			< 6.50
							TRIGLYCERIDES	1.2	mmol/L			0.57 - 2.28
							URIC ACID	238	µmol/L			< 357
			V6 (WEEK 52)	363	15MAR2011	8:25	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	23.6	mmol/L			22.0 - 29.0
							UREA	3.51	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	034	9	V6 (WEEK 52)	363	15MAR2011	8:25	CREATININE	72.5	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	7.9	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	41.9	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE	76	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	6.32	mmol/L			< 6.50
							TRIGLYCERIDES	1.33	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	399	20APR2011	8:25	URIC ACID	208	µmol/L			< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	27.5	mmol/L			22.0 - 29.0
							UREA	2.67	mmol/L			< 8.40
							CREATININE	73.4	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	034	9	V7 (WEEK 56)	399	20APR2011	8:25	GLUCOSE	5.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	45.9	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	77	U/L			35 - 105
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	6.5	mmol/L	HIGH	NCS	< 6.50
	041	12	SCREENING	-16	23SEP2009	10:30	TRIGLYCERIDES	1.58	mmol/L			0.57 - 2.28
							URIC ACID	214	µmol/L			< 357
							SODIUM	141	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26.1	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	55	µmol/L			< 106
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	0.7	mmol/L			0.8 - 1.6
							GLUCOSE	5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	041	12	SCREENING	-16	23SEP2009	10:30	TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 50
							SGPT (ALT)	17	U/L			< 50
							ALKALINE PHOSPHATASE	69	U/L			40 - 130
							GAMMA-GT	25	U/L			< 60
							CHOLESTEROL	5.02	mmol/L			< 6.50
							TRIGLYCERIDES	0.92	mmol/L			0.57 - 2.28
							URIC ACID	333	µmol/L			< 416
							T3	1.39	nmol/L			1.2 - 3.1
							T4	77.4	nmol/L			65.8 - 182
							TSH	1.79	mU/L			0.27 - 4.20
							B12	176	pmol/L			145 - 639
							FOLATE	11.8	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	09OCT2009	13:15	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	58	µmol/L			< 106
							CALCIUM	2.7	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	041	12	V1 (WEEK 0)	1	09OCT2009	13:15	GLUCOSE	7.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	17	U/L			< 50
							ALKALINE	78	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	23	U/L			< 60
							CHOLESTEROL	4.66	mmol/L			< 6.50
							TRIGLYCERIDES	1.01	mmol/L			0.57 - 2.28
		V3 (WEEK 12)	89	05JAN2010	9:40	URIC ACID	303	µmol/L	< 416			
						SODIUM	143	mmol/L	135 - 150			
						POTASSIUM	4.5	mmol/L	3.6 - 5.4			
						CHLORIDE	101	mmol/L	95 - 105			
						BICARBONATE	23.4	mmol/L	22.0 - 29.0			
						UREA	5.34	mmol/L	< 8.40			
						CREATININE	66	µmol/L	< 106			
						CALCIUM	2.4	mmol/L	2.1 - 2.7			
						PHOSPHATE	0.7	mmol/L	0.8 - 1.6			
						GLUCOSE	5.5	mmol/L	2.78 - 5.55			
						TOTAL BILIRUBIN	5.1	µmol/L	< 17.0			
TOTAL PROTEIN	64	g/L	61.0 - 81.0									

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	041	12	V3 (WEEK 12)	89	05JAN2010	9:40	ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 50
							SGPT (ALT)	21	U/L			< 50
							ALKALINE PHOSPHATASE	58	U/L			40 - 130
							GAMMA-GT	102	U/L	HIGH	NCS	< 60
							CHOLESTEROL	5.67	mmol/L			< 6.50
							TRIGLYCERIDES	0.64	mmol/L			0.57 - 2.28
							URIC ACID	309	µmol/L			< 416
			V4 (WEEK 24)	167	24MAR2010	9:10	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	77	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	5.89	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	041	12	V4 (WEEK 24)	167	24MAR2010	9:10	ALKALINE PHOSPHATASE	50	U/L			40 - 130
			V5 (WEEK 36)	251	16JUN2010	9:15	GAMMA-GT	44	U/L			< 60
							CHOLESTEROL	5.96	mmol/L			< 6.50
							TRIGLYCERIDES	0.71	mmol/L			0.57 - 2.28
							URIC ACID	327	µmol/L			< 416
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	25.5	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	75	µmol/L			< 106
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 50
							SGPT (ALT)	15	U/L			< 50
							ALKALINE PHOSPHATASE	51	U/L			40 - 130
							GAMMA-GT	46	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	041	12	V5 (WEEK 36)	251	16JUN2010	9:15	CHOLESTEROL	6.14	mmol/L			< 6.50
							TRIGLYCERIDES	0.7	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 416
			V6 (WEEK 52)	363	06OCT2010	8:30	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	75.1	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 50
							SGPT (ALT)	15	U/L			< 50
							ALKALINE PHOSPHATASE	54	U/L			40 - 130
							GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	5.85	mmol/L			< 6.50
							TRIGLYCERIDES	0.75	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	041	12	V7 (WEEK 56)	392	04NOV2010	8:30	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	27	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	68.1	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 50
							SGPT (ALT)	12	U/L			< 50
							ALKALINE PHOSPHATASE	60	U/L			40 - 130
							GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	5.31	mmol/L			< 6.50
							TRIGLYCERIDES	0.71	mmol/L			0.57 - 2.28
							URIC ACID	345	µmol/L			< 416
	044	12	SCREENING	-28	04NOV2009	9:25	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	044	12	SCREENING	-28	04NOV2009	9:25	CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	24	mmol/L			22.0 - 29.0
							UREA	7.01	mmol/L			< 8.40
							CREATININE	48	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	3.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE	82	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	5.36	mmol/L			< 6.50
							TRIGLYCERIDES	1.33	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 357
							T3	2.05	nmol/L			1.2 - 3.1
							T4	112.2	nmol/L			65.8 - 182
							TSH	0.6	mU/L			0.27 - 4.20
							B12	246	pmol/L			145 - 639
							FOLATE	11.6	nmol/L			10.4 - 42.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	044	12	SCREENING V1 (WEEK 0)	-28 1	04NOV2009 02DEC2009	9:25 9:40	BETA-HCG SERUM	2	U/L			< 5.0
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	47	µmol/L			< 97
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.61	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	82	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	4.84	mmol/L			< 6.50
							TRIGLYCERIDES	1.41	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
			V3 (WEEK 12)	85	24FEB2010	9:20	SODIUM	147	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	044	12	V3 (WEEK 12)	85	24FEB2010	9:20	CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	7.52	mmol/L			< 8.40
							CREATININE	57	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE	69	U/L			35 - 105
			V4 (WEEK 24)	176	26MAY2010	8:30	PHOSPHATASE					
							GAMMA-GT	8	U/L			< 40
							CHOLESTEROL	5.67	mmol/L			< 6.50
							TRIGLYCERIDES	0.89	mmol/L			0.57 - 2.28
							URIC ACID	143	µmol/L			< 357
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	044	12	V4 (WEEK 24)	176	26MAY2010	8:30	CREATININE	59	µmol/L			< 97
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	46.5	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE	71	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	8	U/L			< 40
							CHOLESTEROL	5.96	mmol/L			< 6.50
							TRIGLYCERIDES	0.89	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	260	18AUG2010	8:30	URIC ACID	238	µmol/L			< 357
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	044	12	V5 (WEEK 36)	260	18AUG2010	8:30	GLUCOSE	4.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	64	U/L			35 - 105
							GAMMA-GT	9	U/L			< 40
							CHOLESTEROL	6.03	mmol/L			< 6.50
							TRIGLYCERIDES	1.07	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 357
		V6 (WEEK 52)		365	01DEC2010	8:15	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	27.7	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	53.9	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.39	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	62	g/L			61.0 - 81.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	044	12	V6 (WEEK 52)	365	01DEC2010	8:15	ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35
							ALKALINE PHOSPHATASE	68	U/L			35 - 105
							GAMMA-GT	9	U/L			< 40
							CHOLESTEROL	5	mmol/L			< 6.50
							TRIGLYCERIDES	0.98	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	400	05JAN2011	9:10	URIC ACID	250	µmol/L			< 357
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	28.1	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	52.2	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.12	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	44.1	g/L			35.0 - 55.0
							SGOT (AST)	16	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	044	12	V7 (WEEK 56)	400	05JAN2011	9:10	ALKALINE PHOSPHATASE	64	U/L			35 - 105
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	4.79	mmol/L			< 6.50
							TRIGLYCERIDES	0.92	mmol/L			0.57 - 2.28
							URIC ACID	196	µmol/L			< 357
	045	11	SCREENING	-14	07DEC2009	9:45	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 106
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	38	U/L			10 - 50
							SGPT (ALT)	27	U/L			< 50
							ALKALINE PHOSPHATASE	65	U/L			40 - 130

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	045	11	SCREENING	-14	07DEC2009	9:45	GAMMA-GT	17	U/L			< 60
							CHOLESTEROL	4.25	mmol/L			< 6.50
							TRIGLYCERIDES	0.73	mmol/L			0.57 - 2.28
							URIC ACID	345	µmol/L			< 416
							T3	1.66	nmol/L			1.2 - 3.1
							T4	95.5	nmol/L			65.8 - 182
							TSH	1.07	mU/L			0.27 - 4.20
							B12	572	pmol/L			145 - 639
			V1 (WEEK 0)	1	21DEC2009	9:15	FOLATE	45.3	nmol/L	HIGH	NCS	10.4 - 42.4
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.6	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	76	µmol/L			< 106
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	38	U/L			10 - 50
							SGPT (ALT)	29	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	045	11	V1 (WEEK 0)	1	21DEC2009	9:15	ALKALINE PHOSPHATASE	68	U/L			40 - 130
							GAMMA-GT	18	U/L			< 60
							CHOLESTEROL	4.07	mmol/L			< 6.50
							TRIGLYCERIDES	1.13	mmol/L			0.57 - 2.28
							URIC ACID	351	µmol/L			< 416
			V3 (WEEK 12)	85	15MAR2010	8:30	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	23.7	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	111	µmol/L	HIGH	NCS	< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	3.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE PHOSPHATASE	61	U/L			40 - 130
							GAMMA-GT	14	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	045	11	V3 (WEEK 12)	85	15MAR2010	8:30	CHOLESTEROL	3.42	mmol/L			< 6.50
							TRIGLYCERIDES	0.63	mmol/L			0.57 - 2.28
							URIC ACID	309	µmol/L			< 416
			V4 (WEEK 24)	169	07JUN2010	9:45	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	19.5	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	85	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	35	U/L			10 - 50
							SGPT (ALT)	34	U/L			< 50
							ALKALINE	55	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	16	U/L			< 60
							CHOLESTEROL	3.83	mmol/L			< 6.50
							TRIGLYCERIDES	0.78	mmol/L			0.57 - 2.28
							URIC ACID	399	µmol/L			< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	045	11	V5 (WEEK 36)	260	06SEP2010	9:15	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	26.7	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	88	µmol/L			< 106
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	36	U/L			10 - 50
							SGPT (ALT)	34	U/L			< 50
							ALKALINE PHOSPHATASE	66	U/L			40 - 130
							GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	4.74	mmol/L			< 6.50
							TRIGLYCERIDES	1.21	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L			< 416
			V6 (WEEK 52)	360	15DEC2010	8:30	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	045	11	V6 (WEEK 52)	360	15DEC2010	8:30	BICARBONATE	25.1	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	84.9	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	3.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	27	U/L			< 50
							ALKALINE	65	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	11	U/L			< 60
							CHOLESTEROL	4.22	mmol/L			< 6.50
							TRIGLYCERIDES	0.75	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	393	17JAN2011	9:05	URIC ACID	327	µmol/L			< 416
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	84	µmol/L			59.2 - 103.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	045	11	V7 (WEEK 56)	393	17JAN2011	9:05	CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	25	U/L			< 50
							ALKALINE PHOSPHATASE	65	U/L			40 - 130
							GAMMA-GT	16	U/L			< 60
							CHOLESTEROL	4.58	mmol/L			< 6.50
							TRIGLYCERIDES	1.09	mmol/L			0.57 - 2.28
							URIC ACID	333	µmol/L			< 416
	047	11	SCREENING	-21	12JUL2010	7:55	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	20.5	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	88	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	047	11	SCREENING	-21	12JUL2010	7:55	GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	31	U/L			10 - 50
							SGPT (ALT)	29	U/L			< 50
							ALKALINE PHOSPHATASE	47	U/L			40 - 130
							GAMMA-GT	25	U/L			< 60
							CHOLESTEROL	3.65	mmol/L			< 6.50
							TRIGLYCERIDES	1.39	mmol/L			0.57 - 2.28
							URIC ACID	470	µmol/L	HIGH	NCS	< 416
							T3	1.17	nmol/L	LOW	NCS	1.2 - 3.1
							T4	85.1	nmol/L			65.8 - 182
							TSH	0.69	mU/L			0.27 - 4.20
							B12	406	pmol/L			145 - 639
			V1 (WEEK 0)	1	02AUG2010	8:45	FOLATE	23.1	nmol/L			10.4 - 42.4
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	23.7	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	95	µmol/L			< 106

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	047	11	V1 (WEEK 0)	1	02AUG2010	8:45	CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	32	U/L			< 50
							ALKALINE PHOSPHATASE	48	U/L			40 - 130
							GAMMA-GT	23	U/L			< 60
							CHOLESTEROL	3.19	mmol/L			< 6.50
							TRIGLYCERIDES	1.52	mmol/L			0.57 - 2.28
							V3 (WEEK 12)	80	20OCT2010	11:40	URIC ACID	422
		SODIUM	144	mmol/L							135 - 150	
		POTASSIUM	4.8	mmol/L							3.6 - 5.4	
		CHLORIDE	101	mmol/L							95 - 105	
		BICARBONATE	24.8	mmol/L							22.0 - 29.0	
		UREA	6.35	mmol/L							< 8.40	
		CREATININE	97.2	µmol/L							59.2 - 103.4	
		CALCIUM	2.4	mmol/L							2.1 - 2.7	
		PHOSPHATE	1.1	mmol/L							0.8 - 1.6	
		GLUCOSE	4.45	mmol/L			2.78 - 5.55					

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	047	11	V3 (WEEK 12)	80	20OCT2010	11:40	TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE PHOSPHATASE	47	U/L			40 - 130
							GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	3.83	mmol/L			< 6.50
							TRIGLYCERIDES	2.72	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	422	µmol/L	HIGH	NCS	< 416
			V4 (WEEK 24)	162	10JAN2011	9:30	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	26.9	mmol/L			22.0 - 29.0
							UREA	6.18	mmol/L			< 8.40
							CREATININE	102.5	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	047	11	V4 (WEEK 24)	162	10JAN2011	9:30	SGOT (AST)	34	U/L			10 - 50
							SGPT (ALT)	36	U/L			< 50
							ALKALINE PHOSPHATASE	45	U/L			40 - 130
							GAMMA-GT	27	U/L			< 60
							CHOLESTEROL	4.14	mmol/L			< 6.50
							TRIGLYCERIDES	2.3	mmol/L	HIGH	NCS	0.57 - 2.28
			V5 (WEEK 36)	254	12APR2011	9:15	URIC ACID	464	µmol/L	HIGH	NCS	< 416
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	6.85	mmol/L			< 8.40
							CREATININE	107	µmol/L	HIGH	NCS	59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	78	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	36	U/L			10 - 50
							SGPT (ALT)	41	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	047	11	V5 (WEEK 36)	254	12APR2011	9:15	ALKALINE PHOSPHATASE	51	U/L			40 - 130
			V6 (WEEK 52)	360	27JUL2011	7:35	GAMMA-GT	25	U/L			< 60
							CHOLESTEROL	3.76	mmol/L			< 6.50
							TRIGLYCERIDES	1.9	mmol/L			0.57 - 2.28
							URIC ACID	482	µmol/L	HIGH	NCS	< 416
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	25.6	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	102.5	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.61	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	33	U/L			10 - 50
							SGPT (ALT)	39	U/L			< 50
							ALKALINE PHOSPHATASE	44	U/L			40 - 130
							GAMMA-GT	21	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	047	11	V6 (WEEK 52)	360	27JUL2011	7:35	CHOLESTEROL	3.57	mmol/L			< 6.50
							TRIGLYCERIDES	1.37	mmol/L			0.57 - 2.28
							URIC ACID	470	µmol/L	HIGH	NCS	< 416
			V7 (WEEK 56)	393	29AUG2011	7:45	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	100.8	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	44.2	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 50
							SGPT (ALT)	33	U/L			< 50
							ALKALINE PHOSPHATASE	46	U/L			40 - 130
							GAMMA-GT	27	U/L			< 60
							CHOLESTEROL	3.76	mmol/L			< 6.50
							TRIGLYCERIDES	1.3	mmol/L			0.57 - 2.28
							URIC ACID	452	µmol/L	HIGH	NCS	< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	049	21	SCREENING	-51	06SEP2010	10:45	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	94	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	25.4	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	80	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	19	U/L			< 35
							ALKALINE	85	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	7.98	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.25	mmol/L			0.57 - 2.28
							URIC ACID	363	µmol/L	HIGH	NCS	< 357
							T3	1.49	nmol/L			1.2 - 3.1
							T4	96.8	nmol/L			65.8 - 182
							TSH	2.12	mU/L			0.27 - 4.20

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	049	21	SCREENING	-51	06SEP2010	10:45	B12	264	pmol/L			145 - 639
							FOLATE	40.1	nmol/L			10.4 - 42.4
						BETA-HCG SERUM	4.5	U/L			< 5.0	
			V1 (WEEK 0)	1	27OCT2010	8:55	SODIUM	144	mmol/L			135 - 150
		POTASSIUM					3.8	mmol/L			3.6 - 5.4	
		CHLORIDE					100	mmol/L			95 - 105	
		BICARBONATE					27.3	mmol/L			22.0 - 29.0	
		UREA					6.18	mmol/L			< 8.40	
		CREATININE					90.2	µmol/L	HIGH	NCS	45.1 - 84.0	
		CALCIUM					2.3	mmol/L			2.1 - 2.7	
		PHOSPHATE					1.2	mmol/L			0.8 - 1.6	
		GLUCOSE					3.95	mmol/L			2.78 - 5.55	
		TOTAL BILIRUBIN					5.1	µmol/L			< 17.0	
		TOTAL PROTEIN					70	g/L			61.0 - 81.0	
		ALBUMIN					46	g/L			35.0 - 55.0	
		SGOT (AST)					27	U/L			10 - 35	
		SGPT (ALT)					22	U/L			< 35	
		ALKALINE					88	U/L			35 - 105	
		PHOSPHATASE										
		GAMMA-GT					8	U/L			< 40	
		CHOLESTEROL					7.54	mmol/L	HIGH	NCS	< 6.50	
		TRIGLYCERIDES					0.79	mmol/L			0.57 - 2.28	
		URIC ACID	375	µmol/L	HIGH	NCS	< 357					

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	049	21	V3 (WEEK 12)	84	18JAN2011	10:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.9	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	80.4	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	36	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	88	U/L			35 - 105
							GAMMA-GT	8	U/L			< 40
							CHOLESTEROL	7.82	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.95	mmol/L			0.57 - 2.28
							URIC ACID	381	µmol/L	HIGH	NCS	< 357
			V4 (WEEK 24)	168	12APR2011	11:00	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	049	21	V4 (WEEK 24)	168	12APR2011	11:00	BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	81.3	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE PHOSPHATASE	80	U/L			35 - 105
							GAMMA-GT	10	U/L			< 40
			V5 (WEEK 36)	252	05JUL2011	10:00	CHOLESTEROL	7.51	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.9	mmol/L			0.57 - 2.28
							URIC ACID	339	µmol/L			< 357
							SODIUM	135	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	22	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	71.6	µmol/L			45.1 - 84.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	049	21	V5 (WEEK 36)	252	05JUL2011	10:00	CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	38	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	23	U/L			< 35
							ALKALINE PHOSPHATASE	81	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	5.52	mmol/L			< 6.50
							TRIGLYCERIDES	1.3	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L	HIGH	NCS	< 357
	051	21	SCREENING	-52	06SEP2010	12:40	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	22	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	88	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	051	21	SCREENING	-52	06SEP2010	12:40	GLUCOSE	5.06	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	69	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	4.74	mmol/L			< 6.50
							TRIGLYCERIDES	1.85	mmol/L			0.57 - 2.28
							URIC ACID	410	µmol/L	HIGH	NCS	< 357
							T3	1.17	nmol/L	LOW	NCS	1.2 - 3.1
							T4	120	nmol/L			65.8 - 182
							TSH	5.51	mU/L	HIGH	NCS	0.27 - 4.20
							B12	164	pmol/L			145 - 639
							FOLATE	12	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1.4	U/L			< 5.0
			V1 (WEEK 0)	1	28OCT2010	11:30	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	25.7	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range		
					Date	Time								
Placebo	051	21	V1 (WEEK 0)	1	28OCT2010	11:30	CREATININE	88.4	µmol/L	HIGH	NCS	45.1 - 84.0		
							CALCIUM	2.3	mmol/L			2.1 - 2.7		
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6		
							GLUCOSE	4.84	mmol/L			2.78 - 5.55		
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0		
							TOTAL PROTEIN	70	g/L			61.0 - 81.0		
							ALBUMIN	46.2	g/L			35.0 - 55.0		
							SGOT (AST)	18	U/L			10 - 35		
							SGPT (ALT)	14	U/L			< 35		
							ALKALINE	66	U/L			35 - 105		
							PHOSPHATASE							
							GAMMA-GT	12	U/L			< 40		
							CHOLESTEROL	5.26	mmol/L			< 6.50		
							TRIGLYCERIDES	2.39	mmol/L			HIGH	NCS	0.57 - 2.28
							URIC ACID	458	µmol/L					< 357
			V3 (WEEK 12)	97	01FEB2011	11:30	SODIUM	143	mmol/L	HIGH	NCS	135 - 150		
							POTASSIUM	4.4	mmol/L			3.6 - 5.4		
							CHLORIDE	101	mmol/L			95 - 105		
							BICARBONATE	26.2	mmol/L			22.0 - 29.0		
							UREA	4.84	mmol/L			< 8.40		
							CREATININE	91.9	µmol/L			45.1 - 84.0		
							CALCIUM	2.4	mmol/L			2.1 - 2.7		
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6		

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	051	21	V3 (WEEK 12)	97	01FEB2011	11:30	GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L		< 17.0	
							TOTAL PROTEIN	72	g/L		61.0 - 81.0	
							ALBUMIN	46.3	g/L		35.0 - 55.0	
							SGOT (AST)	23	U/L		10 - 35	
							SGPT (ALT)	20	U/L		< 35	
							ALKALINE PHOSPHATASE	74	U/L		35 - 105	
							GAMMA-GT	15	U/L		< 40	
							CHOLESTEROL	4.77	mmol/L		< 6.50	
							TRIGLYCERIDES	1.94	mmol/L		0.57 - 2.28	
							URIC ACID	488	µmol/L	HIGH	NCS	< 357
			V4 (WEEK 24)	167	12APR2011	13:30	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	29.3	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	111.4	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	6.51	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	051	21	V4 (WEEK 24)	167	12APR2011	13:30	ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE PHOSPHATASE	65	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	4.3	mmol/L			< 6.50
							TRIGLYCERIDES	2.98	mmol/L	HIGH	NCS	0.57 - 2.28
			V5 (WEEK 36)	251	05JUL2011	13:42	URIC ACID	482	µmol/L	HIGH	NCS	< 357
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	21.9	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	84.9	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	051	21	V5 (WEEK 36)	251	05JUL2011	13:42	ALKALINE PHOSPHATASE	60	U/L			35 - 105
			V6 (WEEK 52)	363	25OCT2011	8:30	GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	4.45	mmol/L			< 6.50
							TRIGLYCERIDES	2.55	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	458	µmol/L	HIGH	NCS	< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	97.2	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.1	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	14	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	63	U/L			35 - 105
							GAMMA-GT	12	U/L			< 40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	051	21	V6 (WEEK 52)	363	25OCT2011	8:30	CHOLESTEROL	4.45	mmol/L			< 6.50
							TRIGLYCERIDES	2.12	mmol/L			0.57 - 2.28
							URIC ACID	458	µmol/L	HIGH	NCS	< 357
			V7 (WEEK 56)	391	22NOV2011	8:30	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	24.9	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	100.8	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	15	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	66	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	4.4	mmol/L			< 6.50
							TRIGLYCERIDES	2.61	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	440	µmol/L	HIGH	NCS	< 357

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	056	5	SCREENING	-21	31MAR2010	10:00	SODIUM	133	mmol/L	LOW	NCS	135 - 150
							SODIUM	134	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	23.1	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	61	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	47	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	5.83	mmol/L			< 6.50
							TRIGLYCERIDES	1.01	mmol/L			0.57 - 2.28
							URIC ACID	226	µmol/L			< 357
							T3	0.91	nmol/L	LOW	NCS	1.2 - 3.1
							T4	82.6	nmol/L			65.8 - 182

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	056	5	SCREENING	-21	31MAR2010	10:00	TSH	0.96	mU/L			0.27 - 4.20
							B12	484	pmol/L			145 - 639
							FOLATE	20.4	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	21APR2010	9:15	BETA-HCG SERUM	3.3	U/L			< 5.0
							SODIUM	133	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	92	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	62	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	46.1	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	45	U/L			35 - 105
							GAMMA-GT	21	U/L			< 40
							CHOLESTEROL	5.65	mmol/L			< 6.50
							TRIGLYCERIDES	0.88	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	056	5	V1 (WEEK 0)	1	21APR2010	9:15	URIC ACID	244	µmol/L			< 357
			V3 (WEEK 12)	84	13JUL2010	11:15	SODIUM	133	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	23.9	mmol/L			22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	55	µmol/L			< 97
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	72	U/L			35 - 105
							GAMMA-GT	19	U/L			< 40
							CHOLESTEROL	5.54	mmol/L			< 6.50
							TRIGLYCERIDES	1.12	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 357
			V4 (WEEK 24)	168	05OCT2010	9:15	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	056	5	V4 (WEEK 24)	168	05OCT2010	9:15	CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	57.5	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
			V5 (WEEK 36)	259	04JAN2011	8:50	SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE	51	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	24	U/L			< 40
							CHOLESTEROL	5.88	mmol/L			< 6.50
							TRIGLYCERIDES	0.97	mmol/L			0.57 - 2.28
							URIC ACID	208	µmol/L			< 357
							SODIUM	137	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	93	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	23.1	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	056	5	V5 (WEEK 36)	259	04JAN2011	8:50	CREATININE	58.3	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	23.9	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	44.7	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE	48	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.27	mmol/L			< 6.50
							TRIGLYCERIDES	1.07	mmol/L			0.57 - 2.28
			V6 (WEEK 52)	364	19APR2011	8:05	URIC ACID	244	µmol/L			< 357
							SODIUM	134	mmol/L	LOW	NCS	135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	61	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	056	5	V6 (WEEK 52)	364	19APR2011	8:05	GLUCOSE	5.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	22.2	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	14	U/L			< 35
							ALKALINE PHOSPHATASE	39	U/L			35 - 105
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	5.57	mmol/L			< 6.50
							TRIGLYCERIDES	0.87	mmol/L			0.57 - 2.28
							URIC ACID	262	µmol/L			< 357
	058	1	SCREENING	-21	06DEC2010	10:00	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	91.9	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	058	1	SCREENING	-21	06DEC2010	10:00	TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	17	U/L			< 50
							ALKALINE PHOSPHATASE	64	U/L			40 - 130
							GAMMA-GT	36	U/L			< 60
							CHOLESTEROL	7.54	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.97	mmol/L			0.57 - 2.28
							URIC ACID	399	µmol/L			< 416
							T3	1.63	nmol/L			1.2 - 3.1
							T4	78.7	nmol/L			65.8 - 182
							TSH	0.89	mU/L			0.27 - 4.20
							B12	178	pmol/L			145 - 639
							FOLATE	16.3	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	27DEC2010	11:15	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	22.1	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	89.3	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	058	1	V1 (WEEK 0)	1	27DEC2010	11:15	GLUCOSE	4.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L		< 17.0	
							TOTAL PROTEIN	73	g/L		61.0 - 81.0	
							ALBUMIN	45	g/L		35.0 - 55.0	
							SGOT (AST)	29	U/L		10 - 50	
							SGPT (ALT)	19	U/L		< 50	
							ALKALINE	69	U/L		40 - 130	
							PHOSPHATASE					
							GAMMA-GT	42	U/L		< 60	
							CHOLESTEROL	7.49	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2	mmol/L			0.57 - 2.28
		V3 (WEEK 12)	93	29MAR2011	11:10	URIC ACID	399	µmol/L		< 416		
						SODIUM	140	mmol/L		135 - 150		
						POTASSIUM	4.4	mmol/L		3.6 - 5.4		
						CHLORIDE	101	mmol/L		95 - 105		
						BICARBONATE	23.5	mmol/L		22.0 - 29.0		
						UREA	5.51	mmol/L		< 8.40		
						CREATININE	96.4	µmol/L		59.2 - 103.4		
						CALCIUM	2.4	mmol/L		2.1 - 2.7		
						PHOSPHATE	0.9	mmol/L		0.8 - 1.6		
						GLUCOSE	4.95	mmol/L		2.78 - 5.55		
						TOTAL BILIRUBIN	5.1	µmol/L		< 17.0		
TOTAL PROTEIN	73	g/L		61.0 - 81.0								

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	058	1	V3 (WEEK 12)	93	29MAR2011	11:10	ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50
							ALKALINE PHOSPHATASE	69	U/L			40 - 130
							GAMMA-GT	31	U/L			< 60
							CHOLESTEROL	6.86	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.29	mmol/L			0.57 - 2.28
			V4 (WEEK 24)	166	10JUN2011	10:15	URIC ACID	416	µmol/L	HIGH	NCS	< 416
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	25	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	96.4	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	4.56	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	43.8	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	058	1	V4 (WEEK 24)	166	10JUN2011	10:15	ALKALINE PHOSPHATASE	62	U/L			40 - 130
							GAMMA-GT	36	U/L			< 60
							CHOLESTEROL	6.58	mmol/L	HIGH	NCS	< 6.50
			V5 (WEEK 36)	260	12SEP2011	10:55	TRIGLYCERIDES	1.09	mmol/L			0.57 - 2.28
							URIC ACID	399	µmol/L			< 416
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	23.4	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	84	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	45.7	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE PHOSPHATASE	64	U/L			40 - 130
							GAMMA-GT	40	U/L			< 60

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	058	1	V5 (WEEK 36)	260	12SEP2011	10:55	CHOLESTEROL	7.1	mmol/L	HIGH	NCS	< 6.50
			V6 (WEEK 52)	345	06DEC2011	9:15	TRIGLYCERIDES	1.58	mmol/L			0.57 - 2.28
							URIC ACID	422	µmol/L	HIGH	NCS	< 416
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	27.7	mmol/L			22.0 - 29.0
							UREA	7.35	mmol/L			< 8.40
							CREATININE	100.8	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	5.23	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 50
							SGPT (ALT)	14	U/L			< 50
							ALKALINE PHOSPHATASE	74	U/L			40 - 130
							GAMMA-GT	36	U/L			< 60
							CHOLESTEROL	6.71	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.58	mmol/L			0.57 - 2.28
							URIC ACID	446	µmol/L	HIGH	NCS	< 416

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	058	1	V7 (WEEK 56)	380	10JAN2012	10:25	SODIUM	140	mmol/L			136 - 145
							POTASSIUM	4.5	mmol/L			3.5 - 5.1
							CHLORIDE	104	mmol/L			98 - 107
							BICARBONATE	26	mmol/L			22.0 - 29.0
							UREA	7.35	mmol/L			2.77 - 8.10
							CREATININE	98.1	µmol/L			61.9 - 106.1
							CALCIUM	2.33	mmol/L			2.15 - 2.55
							PHOSPHATE	0.95	mmol/L			0.81 - 1.45
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 20.5
							TOTAL PROTEIN	71	g/L			66 - 87
							ALBUMIN	44	g/L			35 - 52
							SGOT (AST)	29	U/L			< 50
							SGPT (ALT)	17	U/L			< 50
							ALKALINE PHOSPHATASE	71	U/L			40 - 130
							GAMMA-GT	41	U/L			< 60
							CHOLESTEROL	7.25	mmol/L	HIGH	NCS	< 5.18
							TRIGLYCERIDES	1.24	mmol/L			< 2.28
							URIC ACID	440	µmol/L	HIGH	NCS	202 - 416
	059	1	SCREENING	-2	27DEC2010	13:00	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	059	1	SCREENING	-2	27DEC2010	13:00	CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	23.9	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	99	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	7.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE	66	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	7.04	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.93	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	333	µmol/L			< 416
							T3	1.45	nmol/L			1.2 - 3.1
							T4	95.5	nmol/L			65.8 - 182
							TSH	1.1	mU/L			0.27 - 4.20
							B12	174	pmol/L			145 - 639
							FOLATE	16.5	nmol/L			10.4 - 42.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	059	1	V1 (WEEK 0)	1	29DEC2010	10:05	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	23.3	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	96.4	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	8.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE PHOSPHATASE	67	U/L			40 - 130
			V3 (WEEK 12)	93	31MAR2011	9:40	GAMMA-GT	24	U/L			< 60
							CHOLESTEROL	6.76	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.12	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L			< 416
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	5.1	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	059	1	V3 (WEEK 12)	93	31MAR2011	9:40	BICARBONATE	21.3	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	95.5	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L	HIGH	NCS	2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	6.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	47.2	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 50
							SGPT (ALT)	26	U/L			< 50
							ALKALINE	74	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	31	U/L			< 60
							CHOLESTEROL	6.66	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.75	mmol/L			0.57 - 2.28
			V4 (WEEK 24)	161	07JUN2011	9:00	URIC ACID	369	µmol/L	HIGH	NCS	< 416
							SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	27.9	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	101.7	µmol/L			59.2 - 103.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	059	1	V4 (WEEK 24)	161	07JUN2011	9:00	CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	7.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	47.8	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 50
							SGPT (ALT)	29	U/L			< 50
							ALKALINE PHOSPHATASE	72	U/L			40 - 130
							GAMMA-GT	32	U/L			< 60
							CHOLESTEROL	7.1	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.59	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	327	µmol/L			< 416
			V5 (WEEK 36)	254	08SEP2011	10:15	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.9	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	23.9	mmol/L			22.0 - 29.0
							UREA	6.68	mmol/L			< 8.40
							CREATININE	100.8	µmol/L			59.2 - 103.4
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	6.51	mmol/L	HIGH	NCS	2.78 - 5.55

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	059	1	V5 (WEEK 36)	254	08SEP2011	10:15	TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	20	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE PHOSPHATASE	73	U/L			40 - 130
							GAMMA-GT	36	U/L			< 60
							CHOLESTEROL	6.92	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.21	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	357	µmol/L			< 416
			V6 (WEEK 52)	345	08DEC2011	10:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	28.6	mmol/L			22.0 - 29.0
							UREA	6.85	mmol/L			< 8.40
							CREATININE	89.3	µmol/L			59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	0.7	mmol/L	LOW	NCS	0.8 - 1.6
							GLUCOSE	5.95	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	059	1	V6 (WEEK 52)	345	08DEC2011	10:00	SGOT (AST)	16	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50
							ALKALINE PHOSPHATASE	70	U/L			40 - 130
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	6.53	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.18	mmol/L			0.57 - 2.28
							URIC ACID	315	µmol/L			< 416
			V7 (WEEK 56)	380	12JAN2012	11:00	SODIUM	139	mmol/L			136 - 145
							POTASSIUM	4.8	mmol/L			3.5 - 5.1
							CHLORIDE	104	mmol/L			98 - 107
							BICARBONATE	26.7	mmol/L			22.0 - 29.0
							UREA	7.18	mmol/L			2.77 - 8.10
							CREATININE	89.3	µmol/L			61.9 - 106.1
							CALCIUM	2.34	mmol/L			2.15 - 2.55
							PHOSPHATE	0.96	mmol/L			0.81 - 1.45
							GLUCOSE	6.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 20.5
							TOTAL PROTEIN	69	g/L			66 - 87
							ALBUMIN	45	g/L			35 - 52
							SGOT (AST)	18	U/L			< 50
							SGPT (ALT)	22	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	059	1	V7 (WEEK 56)	380	12JAN2012	11:00	ALKALINE PHOSPHATASE	65	U/L			40 - 130
							GAMMA-GT	29	U/L			< 60
							CHOLESTEROL	6.86	mmol/L	HIGH	NCS	< 5.18
							TRIGLYCERIDES	2.34	mmol/L	HIGH	NCS	< 2.28
							URIC ACID	303	µmol/L			202 - 416
	065	16	SCREENING	-20	10AUG2010	11:20	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	19.8	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	6.17	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50
							ALKALINE PHOSPHATASE	46	U/L			40 - 130

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	065	16	SCREENING	-20	10AUG2010	11:20	GAMMA-GT	32	U/L			< 60
							CHOLESTEROL	5.72	mmol/L			< 6.50
							TRIGLYCERIDES	1.92	mmol/L			0.57 - 2.28
							URIC ACID	464	µmol/L	HIGH	NCS	< 416
							T3	1.62	nmol/L			1.2 - 3.1
							T4	86.4	nmol/L			65.8 - 182
							TSH	0.57	mU/L			0.27 - 4.20
							B12	224	pmol/L			145 - 639
							FOLATE	21.3	nmol/L			10.4 - 42.4
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	17.6	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.51	mmol/L			< 8.40
							CREATININE	72	µmol/L			< 106
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.67	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	76	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	32	U/L			< 50
			V1 (WEEK 0)	1	30AUG2010	9:05						

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	065	16	V1 (WEEK 0)	1	30AUG2010	9:05	ALKALINE PHOSPHATASE	57	U/L			40 - 130
							GAMMA-GT	53	U/L			< 60
							CHOLESTEROL	7.46	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.2	mmol/L			0.57 - 2.28
							URIC ACID	470	µmol/L	HIGH	NCS	< 416
			V3 (WEEK 12)	85	22NOV2010	10:50	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	28.1	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	66.3	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50
							ALKALINE PHOSPHATASE	53	U/L			40 - 130
							GAMMA-GT	38	U/L			< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	065	16	V3 (WEEK 12)	85	22NOV2010	10:50	CHOLESTEROL	5.75	mmol/L			< 6.50
							TRIGLYCERIDES	1.86	mmol/L			0.57 - 2.28
		V4 (WEEK 24)					URIC ACID	351	µmol/L			< 416
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	28.8	mmol/L			22.0 - 29.0
							UREA	3.67	mmol/L			< 8.40
							CREATININE	68.1	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	7.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	71	U/L	HIGH	NCS	10 - 50
							SGPT (ALT)	93	U/L	HIGH	NCS	< 50
							ALKALINE PHOSPHATASE	55	U/L			40 - 130
							GAMMA-GT	75	U/L	HIGH	NCS	< 60
							CHOLESTEROL	5.67	mmol/L			< 6.50
							TRIGLYCERIDES	1.07	mmol/L			0.57 - 2.28
							URIC ACID	339	µmol/L			< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	068	16	SCREENING	-27	26OCT2010	8:55	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			< 8.40
							CREATININE	79.6	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 50
							SGPT (ALT)	23	U/L			< 50
							ALKALINE PHOSPHATASE	73	U/L			40 - 130
							GAMMA-GT	18	U/L			< 60
							CHOLESTEROL	4.53	mmol/L			< 6.50
							TRIGLYCERIDES	0.75	mmol/L			0.57 - 2.28
							URIC ACID	291	µmol/L			< 416
							T3	1.56	nmol/L			1.2 - 3.1
							T4	118.7	nmol/L			65.8 - 182
							TSH	0.94	mU/L			0.27 - 4.20

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	068	16	SCREENING	-27	26OCT2010	8:55	B12	269	pmol/L			145 - 639
							FOLATE	23.8	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	22NOV2010	10:10	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	25.4	mmol/L			22.0 - 29.0
							UREA	7.35	mmol/L			< 8.40
							CREATININE	81.3	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	38	U/L			10 - 50
							SGPT (ALT)	28	U/L			< 50
							ALKALINE PHOSPHATASE	76	U/L			40 - 130
							GAMMA-GT	19	U/L			< 60
							CHOLESTEROL	4.66	mmol/L			< 6.50
							TRIGLYCERIDES	0.71	mmol/L			0.57 - 2.28
							URIC ACID	333	µmol/L			< 416
			V3 (WEEK 12)	81	14FEB2011	9:00	SODIUM	143	mmol/L			135 - 150

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	068	16	V3 (WEEK 12)	81	14FEB2011	9:00	POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	26.4	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	72.5	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	22	U/L			< 50
							ALKALINE PHOSPHATASE	68	U/L			40 - 130
							GAMMA-GT	17	U/L			< 60
			V4 (WEEK 24)	163	03MAY2011	10:30	CHOLESTEROL	6.89	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.03	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 416
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	27.9	mmol/L			22.0 - 29.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	068	16	V4 (WEEK 24)	163	03MAY2011	10:30	UREA	5.18	mmol/L			< 8.40
							CREATININE	78.7	µmol/L			59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	63	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	34	U/L			10 - 50
							SGPT (ALT)	29	U/L			< 50
							ALKALINE PHOSPHATASE	62	U/L			40 - 130
							GAMMA-GT	17	U/L			< 60
							CHOLESTEROL	6.14	mmol/L			< 6.50
							TRIGLYCERIDES	0.68	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	262	10AUG2011	9:10	URIC ACID	291	µmol/L			< 416
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	5.3	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	77.8	µmol/L			59.2 - 103.4
							CALCIUM	2.1	mmol/L			2.1 - 2.7

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	068	16	V5 (WEEK 36)	262	10AUG2011	9:10	PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	71	U/L			40 - 130
							GAMMA-GT	21	U/L			< 60
							CHOLESTEROL	7.17	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.31	mmol/L			0.57 - 2.28
			V6 (WEEK 52)	372	28NOV2011	10:30	URIC ACID	309	µmol/L			< 416
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	26.9	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	56.6	µmol/L	LOW	NCS	59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	068	16	V6 (WEEK 52)	372	28NOV2011	10:30	TOTAL PROTEIN	62	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	19	U/L			< 50
							ALKALINE PHOSPHATASE	101	U/L			40 - 130
							GAMMA-GT	17	U/L			< 60
							CHOLESTEROL	3.76	mmol/L			< 6.50
							TRIGLYCERIDES	0.72	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	414	09JAN2012	11:45	URIC ACID	303	µmol/L			< 416
							SODIUM	140	mmol/L			136 - 145
							POTASSIUM	3.8	mmol/L			3.5 - 5.1
							CHLORIDE	103	mmol/L			98 - 107
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	6.01	mmol/L			2.77 - 8.10
							CREATININE	49.5	µmol/L	LOW	NCS	61.9 - 106.1
							CALCIUM	2.23	mmol/L			2.15 - 2.55
							PHOSPHATE	1.01	mmol/L			0.81 - 1.45
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 20.5
							TOTAL PROTEIN	64	g/L	LOW	NCS	66 - 87
							ALBUMIN	46	g/L			35 - 52
							SGOT (AST)	24	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	068	16	V7 (WEEK 56)	414	09JAN2012	11:45	SGPT (ALT)	16	U/L			< 50
							ALKALINE PHOSPHATASE	77	U/L			40 - 130
							GAMMA-GT	18	U/L			< 60
							CHOLESTEROL	4.71	mmol/L			< 5.18
							TRIGLYCERIDES	1.01	mmol/L			< 2.28
							URIC ACID	244	µmol/L			202 - 416
	069	23	SCREENING	-13	24NOV2010	9:42	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	21	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	4.18	mmol/L			< 8.40
							CREATININE	98.1	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.23	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	20.5	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	42.9	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 50
							SGPT (ALT)	25	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	069	23	SCREENING	-13	24NOV2010	9:42	ALKALINE PHOSPHATASE	80	U/L			40 - 130
							GAMMA-GT	32	U/L			< 60
							CHOLESTEROL	6.84	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.47	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	375	µmol/L			< 416
							T3	1.77	nmol/L			1.2 - 3.1
							T4	98	nmol/L			65.8 - 182
							TSH	1.48	mU/L			0.27 - 4.20
							B12	429	pmol/L			145 - 639
							FOLATE	21.3	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	07DEC2010	12:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	26.4	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	89.3	µmol/L			59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	6.28	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	069	23	V1 (WEEK 0)	1	07DEC2010	12:30	SGOT (AST)	24	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50
							ALKALINE PHOSPHATASE	70	U/L			40 - 130
							GAMMA-GT	23	U/L			< 60
							CHOLESTEROL	6.58	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.42	mmol/L	HIGH	NCS	0.57 - 2.28
			V3 (WEEK 12)	93	09MAR2011	12:20	URIC ACID	369	µmol/L			< 416
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	98	mmol/L			95 - 105
							BICARBONATE	24.2	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	103.4	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.89	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 50
							SGPT (ALT)	33	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	069	23	V3 (WEEK 12)	93	09MAR2011	12:20	ALKALINE PHOSPHATASE	93	U/L			40 - 130
			V4 (WEEK 24)	164	19MAY2011	9:30	GAMMA-GT	78	U/L	HIGH	NCS	< 60
							CHOLESTEROL	6.81	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	3.39	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	470	µmol/L	HIGH	NCS	< 416
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	22.7	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	86.6	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	65	g/L			61.0 - 81.0
							ALBUMIN	39	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	66	U/L	HIGH	NCS	< 50
							ALKALINE PHOSPHATASE	118	U/L			40 - 130
							GAMMA-GT	116	U/L	HIGH	NCS	< 60

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	069	23	V4 (WEEK 24)	164	19MAY2011	9:30	CHOLESTEROL	5.13	mmol/L			< 6.50
							TRIGLYCERIDES	2.15	mmol/L			0.57 - 2.28
							URIC ACID	375	µmol/L			< 416
			V5 (WEEK 36)	261	24AUG2011	11:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	105	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	87.5	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	23	U/L			< 50
							ALKALINE	77	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	32	U/L			< 60
							CHOLESTEROL	6.68	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2.69	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	345	µmol/L			< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	069	23	V6 (WEEK 52)	373	14DEC2011	9:00	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	3.9	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	29.3	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	96.4	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	17.1	µmol/L	HIGH	NCS	< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	27	U/L			< 50
							ALKALINE PHOSPHATASE	87	U/L			40 - 130
							GAMMA-GT	39	U/L			< 60
							CHOLESTEROL	7.23	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	4.02	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	399	µmol/L			< 416
			V7 (WEEK 56)	401	11JAN2012	9:00	SODIUM	141	mmol/L			136 - 145
							POTASSIUM	4	mmol/L			3.5 - 5.1
							CHLORIDE	104	mmol/L			98 - 107

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	069	23	V7 (WEEK 56)	401	11JAN2012	9:00	BICARBONATE	26.9	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			2.77 - 8.10
							CREATININE	96.4	µmol/L			61.9 - 106.1
							CALCIUM	2.26	mmol/L			2.15 - 2.55
							PHOSPHATE	0.99	mmol/L			0.81 - 1.45
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 20.5
							TOTAL PROTEIN	71	g/L			66 - 87
							ALBUMIN	45	g/L			35 - 52
							SGOT (AST)	32	U/L			< 50
							SGPT (ALT)	25	U/L			< 50
							ALKALINE	76	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	46	U/L			< 60
							CHOLESTEROL	6.79	mmol/L	HIGH	NCS	< 5.18
							TRIGLYCERIDES	3.73	mmol/L	HIGH	NCS	< 2.28
							URIC ACID	404	µmol/L			202 - 416
	072	18	SCREENING	-20	01DEC2010	11:10	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.2	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	072	18	SCREENING	-20	01DEC2010	11:10	CREATININE	72.5	µmol/L			45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	83	g/L	HIGH	NCS	61.0 - 81.0
							ALBUMIN	52	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	11	U/L			< 35
							ALKALINE PHOSPHATASE	110	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	7.51	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.36	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
							T3	1.62	nmol/L			1.2 - 3.1
							T4	104.5	nmol/L			65.8 - 182
							TSH	1.54	mU/L			0.27 - 4.20
							B12	191	pmol/L			145 - 639
							FOLATE	29.9	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1.6	U/L			< 5.0
			V1 (WEEK 0)	1	21DEC2010	12:15	SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	072	18	V1 (WEEK 0)	1	21DEC2010	12:15	CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	27.1	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	67.2	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	77	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	9	U/L			< 35
							ALKALINE	101	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	6.63	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.84	mmol/L			0.57 - 2.28
							URIC ACID	262	µmol/L			< 357
			V3 (WEEK 12)	85	15MAR2011	9:55	SODIUM	143	mmol/L		NCS	135 - 150
							POTASSIUM	4.6	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	94	mmol/L	LOW	NCS	95 - 105
							BICARBONATE	25.8	mmol/L		NCS	22.0 - 29.0
							UREA	5.34	mmol/L		NCS	< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	072	18	V3 (WEEK 12)	85	15MAR2011	9:55	CREATININE	69	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.2	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	4.67	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	75	g/L		NCS	61.0 - 81.0
							ALBUMIN	44.3	g/L		NCS	35.0 - 55.0
							SGOT (AST)	19	U/L		NCS	10 - 35
							SGPT (ALT)	11	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	88	U/L		NCS	35 - 105
							GAMMA-GT	11	U/L		NCS	< 40
							CHOLESTEROL	6.6	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	0.86	mmol/L		NCS	0.57 - 2.28
							URIC ACID	303	µmol/L		NCS	< 357
			V4 (WEEK 24)	169	07JUN2011	10:01	SODIUM	145	mmol/L		NCS	135 - 150
							POTASSIUM	4.8	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	103	mmol/L		NCS	95 - 105
							BICARBONATE	29.8	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	5.18	mmol/L		NCS	< 8.40
							CREATININE	74.3	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.6	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.3	mmol/L		NCS	0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	072	18	V4 (WEEK 24)	169	07JUN2011	10:01	GLUCOSE	4.89	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	70	g/L		NCS	61.0 - 81.0
							ALBUMIN	45.9	g/L		NCS	35.0 - 55.0
							SGOT (AST)	22	U/L		NCS	10 - 35
							SGPT (ALT)	10	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	95	U/L		NCS	35 - 105
							GAMMA-GT	10	U/L		NCS	< 40
							CHOLESTEROL	5.83	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	1.05	mmol/L		NCS	0.57 - 2.28
							URIC ACID	280	µmol/L		NCS	< 357
		V5 (WEEK 36)		262	08SEP2011	11:03	SODIUM	147	mmol/L		NCS	135 - 150
							POTASSIUM	4.9	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	105	mmol/L		NCS	95 - 105
							BICARBONATE	28.3	mmol/L		NCS	22.0 - 29.0
							UREA	3.34	mmol/L		NCS	< 8.40
							CREATININE	68.1	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.1	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	4.89	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	71	g/L		NCS	61.0 - 81.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	072	18	V5 (WEEK 36)	262	08SEP2011	11:03	ALBUMIN	45	g/L		NCS	35.0 - 55.0
							SGOT (AST)	21	U/L		NCS	10 - 35
							SGPT (ALT)	13	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	93	U/L		NCS	35 - 105
							GAMMA-GT	14	U/L		NCS	< 40
							CHOLESTEROL	5.78	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	1.39	mmol/L		NCS	0.57 - 2.28
							URIC ACID	256	µmol/L		NCS	< 357
			V6 (WEEK 52)	360	15DEC2011	9:59	SODIUM	140	mmol/L		NCS	135 - 150
							POTASSIUM	4.2	mmol/L		NCS	3.6 - 5.4
							CHLORIDE	101	mmol/L		NCS	95 - 105
							BICARBONATE	29	mmol/L		NCS	22.0 - 29.0
							UREA	4.18	mmol/L		NCS	< 8.40
							CREATININE	72.5	µmol/L		NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L		NCS	2.1 - 2.7
							PHOSPHATE	1.1	mmol/L		NCS	0.8 - 1.6
							GLUCOSE	4.61	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L		NCS	< 17.0
							TOTAL PROTEIN	77	g/L		NCS	61.0 - 81.0
							ALBUMIN	49	g/L		NCS	35.0 - 55.0
							SGOT (AST)	17	U/L		NCS	10 - 35
							SGPT (ALT)	6	U/L		NCS	< 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	072	18	V6 (WEEK 52)	360	15DEC2011	9:59	ALKALINE PHOSPHATASE	110	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	10	U/L		NCS	< 40
							CHOLESTEROL	6.22	mmol/L		NCS	< 6.50
							TRIGLYCERIDES	1.24	mmol/L		NCS	0.57 - 2.28
			V7 (WEEK 56)	393	17JAN2012	9:27	URIC ACID	274	µmol/L		NCS	< 357
							SODIUM	144	mmol/L		NCS	136 - 145
							POTASSIUM	5.1	mmol/L		NCS	3.5 - 5.1
							CHLORIDE	102	mmol/L		NCS	98 - 107
							BICARBONATE	29.8	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	3.84	mmol/L		NCS	2.77 - 8.10
							CREATININE	78.7	µmol/L		NCS	44.2 - 79.6
							CALCIUM	2.42	mmol/L		NCS	2.15 - 2.55
							PHOSPHATE	1.16	mmol/L		NCS	0.81 - 1.45
							GLUCOSE	5.39	mmol/L		NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L		NCS	< 20.5
							TOTAL PROTEIN	74	g/L		NCS	66 - 87
							ALBUMIN	47	g/L		NCS	35 - 52
							SGOT (AST)	16	U/L		NCS	< 35
							SGPT (ALT)	9	U/L		NCS	< 35
							ALKALINE PHOSPHATASE	99	U/L		NCS	35 - 105
							GAMMA-GT	11	U/L		NCS	< 40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	072	18	V7 (WEEK 56)	393	17JAN2012	9:27	CHOLESTEROL	6.16	mmol/L	HIGH	NCS	< 5.18
							TRIGLYCERIDES	1.37	mmol/L		NCS	< 2.28
							URIC ACID	339	µmol/L		NCS	143 - 339
	079	13	SCREENING	-18	19JUL2010	15:00	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	5	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	29.1	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	66	µmol/L			< 97
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.62	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	47	g/L			35.0 - 55.0
							SGOT (AST)	42	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	53	U/L	HIGH	NCS	< 35
							ALKALINE	91	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	5.18	mmol/L			< 6.50
							TRIGLYCERIDES	1.63	mmol/L			0.57 - 2.28

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	079	13	SCREENING	-18	19JUL2010	15:00	URIC ACID	369	µmol/L	HIGH	NCS	< 357
							T3	1.45	nmol/L			1.2 - 3.1
							T4	76.1	nmol/L			65.8 - 182
							TSH	1.34	mU/L			0.27 - 4.20
							B12	215	pmol/L			145 - 639
							FOLATE	26	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1.4	mU/ml			< 5.0
			V1 (WEEK 0)	1	06AUG2010	9:50	SODIUM	146	mmol/L	HIGH	NCS	135 - 150
							POTASSIUM	5.5	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	24.7	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	67	µmol/L			< 97
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	3.89	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	38	U/L		HIGH	10 - 35
							SGPT (ALT)	55	U/L			< 35
							ALKALINE	94	U/L	HIGH	NCS	35 - 105
							PHOSPHATASE					

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	079	13	V1 (WEEK 0)	1	06AUG2010	9:50	GAMMA-GT	26	U/L			< 40
							CHOLESTEROL	5.02	mmol/L			< 6.50
							TRIGLYCERIDES	2.46	mmol/L	HIGH	NCS	0.57 - 2.28
							URIC ACID	345	µmol/L			< 357
			V3 (WEEK 12)	96	09NOV2010	11:40	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	4.7	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	28.1	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	66.3	µmol/L			45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	50	g/L			35.0 - 55.0
							SGOT (AST)	29	U/L			10 - 35
							SGPT (ALT)	31	U/L			< 35
							ALKALINE PHOSPHATASE	91	U/L			35 - 105
							GAMMA-GT	22	U/L			< 40
							CHOLESTEROL	5.13	mmol/L			< 6.50
							TRIGLYCERIDES	2.04	mmol/L			0.57 - 2.28

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	079	13	V3 (WEEK 12)	96	09NOV2010	11:40	URIC ACID	369	µmol/L	HIGH	NCS	< 357
			V4 (WEEK 24)	175	27JAN2011	13:00	SODIUM	144	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	95	mmol/L			95 - 105
							BICARBONATE	29.3	mmol/L	HIGH	NCS	22.0 - 29.0
							UREA	3.34	mmol/L			< 8.40
							CREATININE	64.5	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.6	mmol/L			0.8 - 1.6
							GLUCOSE	6.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	74	g/L			61.0 - 81.0
							ALBUMIN	49.8	g/L			35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 35
							SGPT (ALT)	37	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	109	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	32	U/L			< 40
							CHOLESTEROL	6.06	mmol/L			< 6.50
							TRIGLYCERIDES	1.52	mmol/L			0.57 - 2.28
							URIC ACID	339	µmol/L			< 357
			V5 (WEEK 36)	249	11APR2011	11:45	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	079	13	V5 (WEEK 36)	249	11APR2011	11:45	CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	25.8	mmol/L			22.0 - 29.0
							UREA	5.68	mmol/L			< 8.40
							CREATININE	65.4	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	45.9	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 35
							SGPT (ALT)	38	U/L	HIGH	NCS	< 35
							ALKALINE	93	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	21	U/L			< 40
							CHOLESTEROL	5.98	mmol/L			< 6.50
							TRIGLYCERIDES	2.11	mmol/L			0.57 - 2.28
							URIC ACID	381	µmol/L	HIGH	NCS	< 357
			V6 (WEEK 52)	320	21JUN2011	11:15	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	25.9	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	079	13	V6 (WEEK 52)	320	21JUN2011	11:15	CREATININE	59.2	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	44.3	g/L			35.0 - 55.0
							SGOT (AST)	36	U/L	HIGH	NCS	10 - 35
							SGPT (ALT)	50	U/L	HIGH	NCS	< 35
							ALKALINE PHOSPHATASE	97	U/L			35 - 105
							GAMMA-GT	24	U/L			< 40
							CHOLESTEROL	6.14	mmol/L			< 6.50
							TRIGLYCERIDES	3.97	mmol/L	HIGH	NCS	0.57 - 2.28
			V7 (WEEK 56)	348	19JUL2011	14:35	URIC ACID	280	µmol/L			< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	28.7	mmol/L			22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40
							CREATININE	69.8	µmol/L			45.1 - 84.0
							CALCIUM	2.6	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	079	13	V7 (WEEK 56)	348	19JUL2011	14:35	GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	49	g/L	HIGH	NCS	35.0 - 55.0
							SGOT (AST)	36	U/L			10 - 35
							SGPT (ALT)	43	U/L			< 35
							ALKALINE PHOSPHATASE	93	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	21	U/L			< 40
							CHOLESTEROL	6.11	mmol/L			< 6.50
							TRIGLYCERIDES	2.26	mmol/L			0.57 - 2.28
							URIC ACID	321	µmol/L			< 357
	082	17	SCREENING	-8	06OCT2010	11:00	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	3.8	mmol/L			3.6 - 5.4
							CHLORIDE	96	mmol/L			95 - 105
							BICARBONATE	25.4	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	76.9	µmol/L			59.2 - 103.4
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	0.8	mmol/L			0.8 - 1.6
							GLUCOSE	4.78	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	082	17	SCREENING	-8	06OCT2010	11:00	TOTAL PROTEIN	60	g/L	LOW	NCS	61.0 - 81.0
							ALBUMIN	39	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 50
							SGPT (ALT)	20	U/L			< 50
							ALKALINE PHOSPHATASE	38	U/L	LOW	NCS	40 - 130
							GAMMA-GT	19	U/L			< 60
							CHOLESTEROL	4.97	mmol/L			< 6.50
							TRIGLYCERIDES	1.3	mmol/L			0.57 - 2.28
							URIC ACID	303	µmol/L			< 416
							T3	1.76	nmol/L			1.2 - 3.1
							T4	108.4	nmol/L			65.8 - 182
							TSH	2.38	mU/L			0.27 - 4.20
							B12	201	pmol/L			145 - 639
							FOLATE	19	nmol/L			10.4 - 42.4
			V1 (WEEK 0)	1	14OCT2010	9:00	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	24.1	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	92.8	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	082	17	V1 (WEEK 0)	1	14OCT2010	9:00	GLUCOSE	8.06	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	27	U/L			< 50
							ALKALINE	55	U/L			40 - 130
							PHOSPHATASE					
							GAMMA-GT	20	U/L			< 60
							CHOLESTEROL	6.16	mmol/L			< 6.50
							TRIGLYCERIDES	1.63	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	84	05JAN2011	12:30	URIC ACID	345	µmol/L	< 416		
							SODIUM	141	mmol/L	135 - 150		
							POTASSIUM	4.3	mmol/L	3.6 - 5.4		
							CHLORIDE	93	mmol/L	95 - 105		
							BICARBONATE	30	mmol/L	22.0 - 29.0		
							UREA	5.34	mmol/L	< 8.40		
							CREATININE	85.7	µmol/L	59.2 - 103.4		
							CALCIUM	2.2	mmol/L	2.1 - 2.7		
							PHOSPHATE	1.1	mmol/L	0.8 - 1.6		
							GLUCOSE	5.17	mmol/L	2.78 - 5.55		
							TOTAL BILIRUBIN	12	µmol/L	< 17.0		
TOTAL PROTEIN	69	g/L	61.0 - 81.0									

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	082	17	V3 (WEEK 12)	84	05JAN2011	12:30	ALBUMIN	43.2	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 50
							SGPT (ALT)	29	U/L			< 50
							ALKALINE PHOSPHATASE	53	U/L			40 - 130
							GAMMA-GT	30	U/L			< 60
							CHOLESTEROL	6.37	mmol/L			< 6.50
							TRIGLYCERIDES	1.5	mmol/L			0.57 - 2.28
			V4 (WEEK 24)	175	06APR2011	9:20	URIC ACID	393	µmol/L			< 416
							SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	6.51	mmol/L			< 8.40
							CREATININE	93.7	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.73	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	75	g/L			61.0 - 81.0
							ALBUMIN	48	g/L			35.0 - 55.0
							SGOT (AST)	32	U/L			10 - 50
							SGPT (ALT)	37	U/L			< 50

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	082	17	V4 (WEEK 24)	175	06APR2011	9:20	ALKALINE PHOSPHATASE	65	U/L			40 - 130
							GAMMA-GT	23	U/L			< 60
							CHOLESTEROL	5.88	mmol/L			< 6.50
							TRIGLYCERIDES	1.62	mmol/L			0.57 - 2.28
							URIC ACID	369	µmol/L			< 416
			V5 (WEEK 36)	252	22JUN2011	11:15	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	25.3	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	99.9	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	13.7	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	44.8	g/L		NCS	35.0 - 55.0
							SGOT (AST)	30	U/L			10 - 50
							SGPT (ALT)	33	U/L			< 50
							ALKALINE PHOSPHATASE	65	U/L			40 - 130
							GAMMA-GT	33	U/L			< 60

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	082	17	V5 (WEEK 36)	252	22JUN2011	11:15	CHOLESTEROL	6.06	mmol/L			< 6.50
							TRIGLYCERIDES	1.41	mmol/L			0.57 - 2.28
							URIC ACID	351	µmol/L			< 416
			V6 (WEEK 52)	364	12OCT2011	9:15	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	27.7	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	91.9	µmol/L			59.2 - 103.4
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	6.62	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	50.5	g/L		NCS	35.0 - 55.0
							SGOT (AST)	26	U/L			10 - 50
							SGPT (ALT)	30	U/L			< 50
							ALKALINE PHOSPHATASE	54	U/L			40 - 130
							GAMMA-GT	30	U/L			< 60
							CHOLESTEROL	6.24	mmol/L			< 6.50
							TRIGLYCERIDES	1.24	mmol/L			0.57 - 2.28
							URIC ACID	422	µmol/L	HIGH	NCS	< 416

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	082	17	V7 (WEEK 56)	407	24NOV2011	9:20	SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	27.5	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	91.1	µmol/L			59.2 - 103.4
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	6.34	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	15.4	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	46	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 50
							SGPT (ALT)	26	U/L			< 50
							ALKALINE PHOSPHATASE	56	U/L			40 - 130
							GAMMA-GT	26	U/L			< 60
							CHOLESTEROL	5.72	mmol/L			< 6.50
							TRIGLYCERIDES	1.54	mmol/L			0.57 - 2.28
							URIC ACID	333	µmol/L			< 416
	084	17	SCREENING	-9	08NOV2010	10:00	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	084	17	SCREENING	-9	08NOV2010	10:00	CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	26.6	mmol/L			22.0 - 29.0
							UREA	6.35	mmol/L			< 8.40
							CREATININE	78.7	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE	62	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	5.65	mmol/L			< 6.50
							TRIGLYCERIDES	1.17	mmol/L			0.57 - 2.28
							URIC ACID	297	µmol/L			< 357
							T3	1.52	nmol/L			1.2 - 3.1
							T4	96.8	nmol/L			65.8 - 182
							TSH	1.7	mU/L			0.27 - 4.20
							B12	348	pmol/L			145 - 639
							FOLATE	27	nmol/L			10.4 - 42.4

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	084	17	SCREENING V1 (WEEK 0)	-9	08NOV2010	10:00	BETA-HCG SERUM	3.3	U/L			< 5.0
				1	17NOV2010	9:15	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	27.8	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	75.1	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	5.56	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	28	U/L			10 - 35
							SGPT (ALT)	13	U/L			< 35
							ALKALINE PHOSPHATASE	55	U/L			35 - 105
							GAMMA-GT	9	U/L			< 40
							CHOLESTEROL	4.95	mmol/L			< 6.50
							TRIGLYCERIDES	1.09	mmol/L			0.57 - 2.28
							URIC ACID	286	µmol/L			< 357
			V3 (WEEK 12)	84	08FEB2011	10:20	SODIUM	146	mmol/L			135 - 150
							POTASSIUM	3.7	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	084	17	V3 (WEEK 12)	84	08FEB2011	10:20	CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	27.3	mmol/L			22.0 - 29.0
							UREA	5.18	mmol/L			< 8.40
							CREATININE	69.8	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	0.9	mmol/L			0.8 - 1.6
							GLUCOSE	4.84	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	10	U/L			< 35
							ALKALINE	87	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	5.7	mmol/L			< 6.50
							TRIGLYCERIDES	1.48	mmol/L			0.57 - 2.28
							URIC ACID	297	µmol/L			< 357
			V4 (WEEK 24)	175	10MAY2011	10:45	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	20.2	mmol/L	LOW	NCS	22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	084	17	V4 (WEEK 24)	175	10MAY2011	10:45	CREATININE	76	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	39.6	g/L			35.0 - 55.0
							SGOT (AST)	25	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE	72	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	15	U/L			< 40
							CHOLESTEROL	5.8	mmol/L			< 6.50
							TRIGLYCERIDES	1.32	mmol/L			0.57 - 2.28
			V5 (WEEK 36)	259	02AUG2011	11:15	URIC ACID	274	µmol/L			< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	4.84	mmol/L			< 8.40
							CREATININE	74.3	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	084	17	V5 (WEEK 36)	259	02AUG2011	11:15	GLUCOSE	4.78	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	17	U/L			< 35
							ALKALINE PHOSPHATASE	60	U/L			35 - 105
							GAMMA-GT	9	U/L			< 40
							CHOLESTEROL	5.49	mmol/L			< 6.50
							TRIGLYCERIDES	1.43	mmol/L			0.57 - 2.28
							URIC ACID	262	µmol/L			< 357
		V6 (WEEK 52)		371	22NOV2011	11:30	SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	26.5	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			< 8.40
							CREATININE	71.6	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	4.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	3.4	µmol/L			< 17.0
							TOTAL PROTEIN	70	g/L			61.0 - 81.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	084	17	V6 (WEEK 52)	371	22NOV2011	11:30	ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	61	U/L			35 - 105
							GAMMA-GT	14	U/L			< 40
							CHOLESTEROL	5.85	mmol/L			< 6.50
							TRIGLYCERIDES	1.24	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	394	15DEC2011	9:32	URIC ACID	274	µmol/L			< 357
							SODIUM	139	mmol/L			135 - 150
							POTASSIUM	4.3	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	27.4	mmol/L			22.0 - 29.0
							UREA	5.85	mmol/L			< 8.40
							CREATININE	86.6	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1	mmol/L			0.8 - 1.6
							GLUCOSE	3.45	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	12	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	49	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	25	U/L			< 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	084	17	V7 (WEEK 56)	394	15DEC2011	9:32	ALKALINE PHOSPHATASE	57	U/L			35 - 105
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	4.84	mmol/L			< 6.50
							TRIGLYCERIDES	1.17	mmol/L			0.57 - 2.28
							URIC ACID	202	µmol/L			< 357
	086	21	SCREENING	-24	04OCT2010	11:05	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	97	mmol/L			95 - 105
							BICARBONATE	23.6	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	75.1	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	46.7	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	66	U/L			35 - 105

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	086	21	SCREENING	-24	04OCT2010	11:05	GAMMA-GT	9	U/L			< 40
							CHOLESTEROL	8	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.98	mmol/L			0.57 - 2.28
							URIC ACID	309	µmol/L			< 357
							T3	1.32	nmol/L			1.2 - 3.1
							T4	121.3	nmol/L			65.8 - 182
							TSH	0.32	mU/L			0.27 - 4.20
							B12	393	pmol/L			145 - 639
							FOLATE	14.9	nmol/L			10.4 - 42.4
							BETA-HCG SERUM	1.9	U/L			< 5.0
			V1 (WEEK 0)	1	28OCT2010	14:05	SODIUM	145	mmol/L			135 - 150
							POTASSIUM	4.8	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	28.5	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	88.4	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.4	mmol/L			0.8 - 1.6
							GLUCOSE	5.84	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	64	g/L			61.0 - 81.0
							ALBUMIN	44.5	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	086	21	V1 (WEEK 0)	1	28OCT2010	14:05	SGPT (ALT)	14	U/L			< 35
							ALKALINE	60	U/L			35 - 105
							PHOSPHATASE					
							GAMMA-GT	9	U/L			< 40
							CHOLESTEROL	7.04	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.89	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	83	18JAN2011	11:30	URIC ACID	357	µmol/L	HIGH	NCS	< 357
							SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	101	mmol/L			95 - 105
							BICARBONATE	25.7	mmol/L			22.0 - 29.0
							UREA	5.51	mmol/L			< 8.40
							CREATININE	79.6	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.67	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	71	g/L			61.0 - 81.0
							ALBUMIN	45	g/L			35.0 - 55.0
							SGOT (AST)	27	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE	53	U/L			35 - 105
							PHOSPHATASE					

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	086	21	V3 (WEEK 12)	83	18JAN2011	11:30	GAMMA-GT	7	U/L			< 40
			V4 (WEEK 24)	167	12APR2011	11:55	CHOLESTEROL	6.84	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.5	mmol/L			0.57 - 2.28
							URIC ACID	363	µmol/L	HIGH	NCS	< 357
							SODIUM	141	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	104	mmol/L			95 - 105
							BICARBONATE	25.4	mmol/L			22.0 - 29.0
							UREA	4.68	mmol/L			< 8.40
							CREATININE	74.3	µmol/L			45.1 - 84.0
							CALCIUM	2.5	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.28	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35
							SGPT (ALT)	16	U/L			< 35
							ALKALINE PHOSPHATASE	65	U/L			35 - 105
							GAMMA-GT	16	U/L			< 40
							CHOLESTEROL	6.99	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.58	mmol/L			0.57 - 2.28

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	086	21	V4 (WEEK 24)	167	12APR2011	11:55	URIC ACID	321	µmol/L			< 357
			V5 (WEEK 36)	251	05JUL2011	11:57	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4.1	mmol/L			3.6 - 5.4
							CHLORIDE	99	mmol/L			95 - 105
							BICARBONATE	23.7	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	65.4	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.5	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35
							SGPT (ALT)	10	U/L			< 35
							ALKALINE PHOSPHATASE	54	U/L			35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	7.1	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.4	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
			V6 (WEEK 52)	363	25OCT2011	11:30	SODIUM	138	mmol/L			135 - 150
							POTASSIUM	4	mmol/L			3.6 - 5.4

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	086	21	V6 (WEEK 52)	363	25OCT2011	11:30	CHLORIDE	100	mmol/L			95 - 105
							BICARBONATE	27.6	mmol/L			22.0 - 29.0
							UREA	4.34	mmol/L			< 8.40
							CREATININE	74.3	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.3	mmol/L			0.8 - 1.6
							GLUCOSE	5.78	mmol/L	HIGH	NCS	2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	68	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	17	U/L			10 - 35
							SGPT (ALT)	8	U/L			< 35
							ALKALINE	65	U/L			35 - 105
			V7 (WEEK 56)	391	22NOV2011	10:10	PHOSPHATASE					
							GAMMA-GT	9	U/L			< 40
							CHOLESTEROL	6.6	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	1.71	mmol/L			0.57 - 2.28
							URIC ACID	333	µmol/L			< 357
							SODIUM	142	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	106	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24	mmol/L			22.0 - 29.0
							UREA	3.84	mmol/L			< 8.40

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	086	21	V7 (WEEK 56)	391	22NOV2011	10:10	CREATININE	71.6	µmol/L			45.1 - 84.0
							CALCIUM	2.2	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.95	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	10.3	µmol/L			< 17.0
							TOTAL PROTEIN	66	g/L			61.0 - 81.0
							ALBUMIN	44	g/L			35.0 - 55.0
							SGOT (AST)	19	U/L			10 - 35
							SGPT (ALT)	12	U/L			< 35
							ALKALINE PHOSPHATASE	60	U/L			35 - 105
							GAMMA-GT	8	U/L			< 40
							CHOLESTEROL	6.79	mmol/L	HIGH	NCS	< 6.50
							TRIGLYCERIDES	2	mmol/L			0.57 - 2.28
							URIC ACID	291	µmol/L			< 357
	088	16	SCREENING	-9	30NOV2010	10:00	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.4	mmol/L			3.6 - 5.4
							CHLORIDE	102	mmol/L			95 - 105
							BICARBONATE	23.8	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	61.9	µmol/L			45.1 - 84.0
							CALCIUM	2.3	mmol/L			2.1 - 2.7

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	088	16	SCREENING	-9	30NOV2010	10:00	PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.39	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	73	g/L			61.0 - 81.0
							ALBUMIN	42	g/L			35.0 - 55.0
							SGOT (AST)	21	U/L			10 - 35
							SGPT (ALT)	21	U/L			< 35
							ALKALINE PHOSPHATASE	132	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	5.52	mmol/L			< 6.50
							TRIGLYCERIDES	0.89	mmol/L			0.57 - 2.28
							URIC ACID	244	µmol/L			< 357
							T3	1.54	nmol/L			1.2 - 3.1
							T4	126.4	nmol/L			65.8 - 182
							TSH	0.49	mU/L			0.27 - 4.20
							B12	306	pmol/L			145 - 639
							FOLATE	10.2	nmol/L	LOW	NCS	10.4 - 42.4
							BETA-HCG SERUM	2.7	U/L			< 5.0
			V1 (WEEK 0)	1	09DEC2010	9:05	SODIUM	140	mmol/L			135 - 150
							POTASSIUM	4.5	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	26.8	mmol/L			22.0 - 29.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	088	16	V1 (WEEK 0)	1	09DEC2010	9:05	UREA	5.18	mmol/L			< 8.40
							CREATININE	70.7	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.73	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 17.0
							TOTAL PROTEIN	72	g/L			61.0 - 81.0
							ALBUMIN	43	g/L			35.0 - 55.0
							SGOT (AST)	24	U/L			10 - 35
							SGPT (ALT)	20	U/L			< 35
							ALKALINE PHOSPHATASE	146	U/L	HIGH	NCS	35 - 105
							GAMMA-GT	12	U/L			< 40
							CHOLESTEROL	5.65	mmol/L			< 6.50
							TRIGLYCERIDES	1.04	mmol/L			0.57 - 2.28
			V3 (WEEK 12)	83	01MAR2011	10:00	URIC ACID	250	µmol/L			< 357
							SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	107	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.7	mmol/L			22.0 - 29.0
							UREA	5.01	mmol/L			< 8.40
							CREATININE	69.8	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	088	16	V3 (WEEK 12)	83	01MAR2011	10:00	PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	5.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0
							TOTAL PROTEIN	69	g/L			61.0 - 81.0
							ALBUMIN	41	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	102	U/L			35 - 105
							GAMMA-GT	11	U/L			< 40
							CHOLESTEROL	5.54	mmol/L			< 6.50
							TRIGLYCERIDES	0.82	mmol/L			0.57 - 2.28
							URIC ACID	280	µmol/L			< 357
		V4 (WEEK 24)		162	19MAY2011	9:30	SODIUM	137	mmol/L			135 - 150
							POTASSIUM	4.2	mmol/L			3.6 - 5.4
							CHLORIDE	103	mmol/L			95 - 105
							BICARBONATE	22.7	mmol/L			22.0 - 29.0
							UREA	3.17	mmol/L			< 8.40
							CREATININE	69.8	µmol/L			45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.1	mmol/L			0.8 - 1.6
							GLUCOSE	4.61	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	6.8	µmol/L			< 17.0

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	088	16	V4 (WEEK 24)	162	19MAY2011	9:30	TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	40	g/L			35.0 - 55.0
							SGOT (AST)	22	U/L			10 - 35
							SGPT (ALT)	15	U/L			< 35
							ALKALINE PHOSPHATASE	86	U/L			35 - 105
							GAMMA-GT	10	U/L			< 40
							CHOLESTEROL	5.1	mmol/L			< 6.50
							TRIGLYCERIDES	1.05	mmol/L			0.57 - 2.28
							URIC ACID	268	µmol/L			< 357
			V5 (WEEK 36)	264	29AUG2011	9:35	SODIUM	143	mmol/L			135 - 150
							POTASSIUM	4.6	mmol/L			3.6 - 5.4
							CHLORIDE	108	mmol/L	HIGH	NCS	95 - 105
							BICARBONATE	24.6	mmol/L			22.0 - 29.0
							UREA	4.01	mmol/L			< 8.40
							CREATININE	84.9	µmol/L	HIGH	NCS	45.1 - 84.0
							CALCIUM	2.4	mmol/L			2.1 - 2.7
							PHOSPHATE	1.2	mmol/L			0.8 - 1.6
							GLUCOSE	4.17	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	5.1	µmol/L			< 17.0
							TOTAL PROTEIN	67	g/L			61.0 - 81.0
							ALBUMIN	39.3	g/L			35.0 - 55.0
							SGOT (AST)	23	U/L			10 - 35

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	088	16	V5 (WEEK 36)	264	29AUG2011	9:35	SGPT (ALT)	27	U/L			< 35
							ALKALINE	126	U/L	HIGH	NCS	35 - 105
							PHOSPHATASE					
							GAMMA-GT	17	U/L			< 40
							CHOLESTEROL	5.78	mmol/L			< 6.50
							TRIGLYCERIDES	0.84	mmol/L			0.57 - 2.28
			V7 (WEEK 56)	404	16JAN2012	9:30	URIC ACID	291	µmol/L			< 357
							SODIUM	146	mmol/L	HIGH	NCS	136 - 145
							POTASSIUM	4.3	mmol/L			3.5 - 5.1
							CHLORIDE	109	mmol/L	HIGH	NCS	98 - 107
							BICARBONATE	25.7	mmol/L			22.0 - 29.0
							UREA	5.34	mmol/L			2.77 - 8.10
							CREATININE	84.9	µmol/L	HIGH	NCS	44.2 - 79.6
							CALCIUM	2.28	mmol/L			2.15 - 2.55
							PHOSPHATE	1.05	mmol/L			0.81 - 1.45
							GLUCOSE	4.34	mmol/L			2.78 - 5.55
							TOTAL BILIRUBIN	8.6	µmol/L			< 20.5
							TOTAL PROTEIN	69	g/L			66 - 87
							ALBUMIN	43	g/L			35 - 52
							SGOT (AST)	22	U/L			< 35
							SGPT (ALT)	18	U/L			< 35
							ALKALINE	92	U/L			35 - 105
							PHOSPHATASE					

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Listing 16.2.8.2: Biochemistry

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	High /Low	Clin. signi- ficant	Reference range
					Date	Time						
Placebo	088	16	V7 (WEEK 56)	404	16JAN2012	9:30	GAMMA-GT	13	U/L			< 40
							CHOLESTEROL	6.37	mmol/L	HIGH	NCS	< 5.18
							TRIGLYCERIDES	0.95	mmol/L			< 2.28
							URIC ACID	220	µmol/L			143 - 339

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	002	1	SCREENING	-7	16APR2009	10:00	ERYTHROCYTES	4.8	/pL		3.8 - 5.3
							HEMOGLOBIN	9.3	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.47	L/L		0.35 - 0.47
							MCH (HbE)	1.95	fmol		1.74 - 1.99
							MCHC	19.8	mmol/L	LOW NCS	19.9 - 22.9
							MCV	98.5	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	240	/nL		150 - 400
							LEUKOCYTES	6.7	/nL		4.0 - 9.0
							NEUTROPHILS	57.1	%		50.0 - 70.0
							LYMPHOCYTES	28.2	%		25.0 - 40.0
							MONOCYTES	9.8	%		2.0 - 14.0
							EOSINOPHILS	4.4	%	HIGH NCS	< 4.0
							BASOPHILS	0.5	%		< 1.0
							LUC	0	%		< 4.0
							INR-VALUE	1.11			0.83 - 1.43
							aPTT	35.4	sec		26.0 - 40.0
							QUICK (VENOUS)	87	%		> 70
			V1 (WEEK 0)	1	23APR2009	8:55	ERYTHROCYTES	4.8	/pL		3.8 - 5.3
							HEMOGLOBIN	9.3	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.46	L/L		0.35 - 0.47
							MCH (HbE)	1.93	fmol		1.74 - 1.99
							MCHC	20.2	mmol/L		19.9 - 22.9
							MCV	95.2	fL		82.0 - 96.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	002	1	V1 (WEEK 0)	1	23APR2009	8:55	THROMBOCYTES	237	/nL		150 - 400
							LEUKOCYTES	7	/nL		4.0 - 9.0
							NEUTROPHILS	57.1	%		50.0 - 70.0
							LYMPHOCYTES	27.9	%		25.0 - 40.0
							MONOCYTES	10.3	%		2.0 - 14.0
							EOSINOPHILS	4.3	%	HIGH NCS	< 4.0
							BASOPHILS	0.4	%		< 1.0
							LUC	0	%		< 4.0
			V3 (WEEK 12)	85	16JUL2009	8:30	ERYTHROCYTES	4.5	/pL		3.8 - 5.3
							HEMOGLOBIN	8.7	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.46	L/L		0.35 - 0.47
							MCH (HbE)	1.91	fmol		1.74 - 1.99
							MCHC	18.9	mmol/L	LOW NCS	19.9 - 22.9
							MCV	101.1	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	184	/nL		150 - 400
							LEUKOCYTES	5.4	/nL		4.0 - 9.0
							NEUTROPHILS	50.4	%		50.0 - 70.0
							LYMPHOCYTES	35.1	%		25.0 - 40.0
							MONOCYTES	8.7	%		2.0 - 14.0
							EOSINOPHILS	5.2	%	HIGH NCS	< 4.0
							BASOPHILS	0.6	%		< 1.0
							LUC	0	%		< 4.0
			V4 (WEEK 24)	169	08OCT2009	10:30	ERYTHROCYTES	4.7	/pL		3.8 - 5.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	002	1	V4 (WEEK 24)	169	08OCT2009	10:30	HEMOGLOBIN	9.2	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.46	L/L		0.35 - 0.47
							MCH (HbE)	1.95	fmol		1.74 - 1.99
							MCHC	20.2	mmol/L		19.9 - 22.9
							MCV	96.6	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	207	/nL		150 - 400
							LEUKOCYTES	7.6	/nL		4.0 - 9.0
							NEUTROPHILS	65.8	%		50.0 - 70.0
							LYMPHOCYTES	21.8	%	LOW NCS	25.0 - 40.0
							MONOCYTES	8.9	%		2.0 - 14.0
							EOSINOPHILS	3	%		< 4.0
							BASOPHILS	0.5	%		< 1.0
			V5 (WEEK 36)	258	05JAN2010	9:25	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 1.99
							MCHC	20.7	mmol/L		19.8 - 22.3
							MCV	94.2	fL		79.4 - 94.8
							THROMBOCYTES	208	/nL		182 - 369
							LEUKOCYTES	6	/nL		4.0 - 10.0
							NEUTROPHILS	52.3	%		34.0 - 71.0
							LYMPHOCYTES	31.8	%		19.0 - 52.0
							MONOCYTES	9.4	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	002	1	V5 (WEEK 36)	258	05JAN2010	9:25	EOSINOPHILS	5.7	%		1.0 - 6.0
							BASOPHILS	0.8	%		< 1.0
			V6 (WEEK 52)	365	22APR2010	10:10	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.3	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	95.8	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	229	/nL		182 - 369
							LEUKOCYTES	8.4	/nL		4.0 - 10.0
							NEUTROPHILS	58.1	%		34.0 - 71.0
							LYMPHOCYTES	28.1	%		19.0 - 52.0
							MONOCYTES	8.5	%		5.0 - 13.0
							EOSINOPHILS	4.8	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V7 (WEEK 56)	393	20MAY2010	9:15	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.92	fmol		1.59 - 2.00
							MCHC	20.7	mmol/L		19.8 - 22.3
							MCV	92.7	fL		79.4 - 94.8
							THROMBOCYTES	245	/nL		182 - 369
							LEUKOCYTES	5.2	/nL		4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	002	1	V7 (WEEK 56)	393	20MAY2010	9:15	NEUTROPHILS	48.6	%		34.0 - 71.0
							LYMPHOCYTES	34.6	%		19.0 - 52.0
							MONOCYTES	10.2	%		5.0 - 13.0
							EOSINOPHILS	6	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
	004	1	SCREENING	-29	17JUN2009	11:40	ERYTHROCYTES	4.6	/pL		4.2 - 5.7
							HEMOGLOBIN	8.8	mmol/L		8.4 - 11.2
							HEMATOCRIT	0.45	L/L		0.39 - 0.55
							MCH (HbE)	1.93	fmol		1.74 - 1.99
							MCHC	19.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	98	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	223	/nL		150 - 400
							LEUKOCYTES	5.1	/nL		4.0 - 9.0
							NEUTROPHILS	66.8	%		50.0 - 70.0
							LYMPHOCYTES	23.5	%	LOW NCS	25.0 - 40.0
							MONOCYTES	6.5	%		2.0 - 14.0
							EOSINOPHILS	2.4	%		< 4.0
							BASOPHILS	0.8	%		< 1.0
							LUC	0	%		< 4.0
							INR-VALUE	0.96			0.83 - 1.43
							aPTT	35.1	sec		26.0 - 40.0
							QUICK (VENOUS)	106	%		> 70

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	004	1	V1 (WEEK 0)	1	16JUL2009	10:00	ERYTHROCYTES	4.3	/pL			4.2 - 5.7
							HEMOGLOBIN	8.4	mmol/L			8.4 - 11.2
							HEMATOCRIT	0.45	L/L			0.39 - 0.55
							MCH (HbE)	1.95	fmol			1.74 - 1.99
							MCHC	18.7	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	104.4	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	241	/nL			150 - 400
							LEUKOCYTES	4.4	/nL			4.0 - 9.0
							NEUTROPHILS	66	%			50.0 - 70.0
							LYMPHOCYTES	24.7	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	5.4	%			2.0 - 14.0
							EOSINOPHILS	3.2	%			< 4.0
							BASOPHILS	0.7	%			< 1.0
							LUC	0	%			< 4.0
			V3 (WEEK 12)	92	15OCT2009	14:50	ERYTHROCYTES	4.5	/pL			4.2 - 5.7
							HEMOGLOBIN	8.7	mmol/L			8.4 - 11.2
							HEMATOCRIT	0.41	L/L			0.39 - 0.55
							MCH (HbE)	1.95	fmol			1.74 - 1.99
							MCHC	21.2	mmol/L			19.9 - 22.9
							MCV	91.9	fL			82.0 - 96.0
							THROMBOCYTES	236	/nL			150 - 400
							LEUKOCYTES	5.9	/nL			4.0 - 9.0
							NEUTROPHILS	65.8	%			50.0 - 70.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	004	1	V3 (WEEK 12)	92	15OCT2009	14:50	LYMPHOCYTES	24.4	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	6.2	%			2.0 - 14.0
							EOSINOPHILS	3.1	%			< 4.0
							BASOPHILS	0.5	%			< 1.0
	006	2	SCREENING	-32	25JAN2010	8:45	ERYTHROCYTES	4.5	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.45	L/L			0.40 - 0.50
							MCH (HbE)	2.1	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	21	mmol/L			19.8 - 22.3
							MCV	100.2	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	231	/nL			163 - 337
							LEUKOCYTES	6.3	/nL			4.2 - 9.1
							NEUTROPHILS	59.8	%			34.0 - 68.0
							LYMPHOCYTES	27.8	%			22.0 - 53.0
							MONOCYTES	11.3	%			5.0 - 12.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.3	%			< 1.0
							INR-VALUE	1.12				0.83 - 1.43
							aPTT	37.6	sec			26.0 - 40.0
							QUICK (VENOUS)	84	%			> 70
			V1 (WEEK 0)	1	26FEB2010	9:00	ERYTHROCYTES	4.5	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	9.6	mmol/L			8.5 - 10.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	006	2	V1 (WEEK 0)	1	26FEB2010	9:00	HEMATOCRIT	0.48	L/L			0.40 - 0.50
							MCH (HbE)	2.11	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	20.2	mmol/L			19.8 - 22.3
							MCV	105.1	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	248	/nL			163 - 337
							LEUKOCYTES	6.3	/nL			4.2 - 9.1
							NEUTROPHILS	56.9	%			34.0 - 68.0
							LYMPHOCYTES	33	%			22.0 - 53.0
							MONOCYTES	9.3	%			5.0 - 12.0
							EOSINOPHILS	0.3	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.5	%			< 1.0
			V3 (WEEK 12)	85	21MAY2010	9:15	ERYTHROCYTES	4.5	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.46	L/L			0.40 - 0.50
							MCH (HbE)	2.04	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	20	mmol/L			19.8 - 22.3
							MCV	102	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	240	/nL			163 - 337
							LEUKOCYTES	6.4	/nL			4.2 - 9.1
							NEUTROPHILS	57.4	%			34.0 - 68.0
							LYMPHOCYTES	32.3	%			22.0 - 53.0
							MONOCYTES	9.1	%			5.0 - 12.0
							EOSINOPHILS	0.6	%	LOW	NCS	1.0 - 7.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	006	2	V3 (WEEK 12)	85	21MAY2010	9:15	BASOPHILS	0.6	%			< 1.0
			V4 (WEEK 24)	169	13AUG2010	9:00	ERYTHROCYTES	4.4	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	9	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.45	L/L			0.40 - 0.50
							MCH (HbE)	2.03	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	19.9	mmol/L			19.8 - 22.3
							MCV	102	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	218	/nL			163 - 337
							LEUKOCYTES	5.2	/nL			4.2 - 9.1
							NEUTROPHILS	57.6	%			34.0 - 68.0
							LYMPHOCYTES	32.1	%			22.0 - 53.0
							MONOCYTES	9.1	%			5.0 - 12.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.4	%			< 1.0
			V5 (WEEK 36)	252	04NOV2010	8:30	ERYTHROCYTES	4.5	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.46	L/L			0.40 - 0.50
							MCH (HbE)	2.11	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	20.7	mmol/L			19.8 - 22.3
							MCV	102	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	244	/nL			163 - 337
							LEUKOCYTES	5.4	/nL			4.2 - 9.1
							NEUTROPHILS	50.6	%			34.0 - 68.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	006	2	V5 (WEEK 36)	252	04NOV2010	8:30	LYMPHOCYTES	37.4	%		22.0 - 53.0
							MONOCYTES	11	%		5.0 - 12.0
							EOSINOPHILS	0.6	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V6 (WEEK 52)	364	24FEB2011	8:20	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	2.06	fmol	HIGH NCS	1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	98.5	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	249	/nL		163 - 337
							LEUKOCYTES	5.9	/nL		4.2 - 9.1
							NEUTROPHILS	53	%		34.0 - 68.0
							LYMPHOCYTES	35.8	%		22.0 - 53.0
							MONOCYTES	10.2	%		5.0 - 12.0
							EOSINOPHILS	0.5	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
			V7 (WEEK 56)	390	22MAR2011	8:30	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.48	L/L		0.40 - 0.50
							MCH (HbE)	2.03	fmol	HIGH NCS	1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	102.8	fL	HIGH NCS	79.0 - 92.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	006	2	V7 (WEEK 56)	390	22MAR2011	8:30	THROMBOCYTES	279	/nL		163 - 337
							LEUKOCYTES	5.1	/nL		4.2 - 9.1
							NEUTROPHILS	53.5	%		34.0 - 68.0
							LYMPHOCYTES	33.7	%		22.0 - 53.0
							MONOCYTES	11.2	%		5.0 - 12.0
							EOSINOPHILS	0.8	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.8	%		< 1.0
	010	1	SCREENING	-26	25JUN2009	9:45	ERYTHROCYTES	4	/pL	LOW NCS	4.2 - 5.7
							HEMOGLOBIN	7.8	mmol/L	LOW NCS	8.4 - 11.2
							HEMATOCRIT	0.4	L/L		0.39 - 0.55
							MCH (HbE)	1.94	fmol		1.74 - 1.99
							MCHC	19.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	99	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	167	/nL		150 - 400
							LEUKOCYTES	6.3	/nL		4.0 - 9.0
							NEUTROPHILS	51.6	%		50.0 - 70.0
							LYMPHOCYTES	36.8	%		25.0 - 40.0
							MONOCYTES	9.7	%		2.0 - 14.0
							EOSINOPHILS	1.6	%		< 4.0
							BASOPHILS	0.3	%		< 1.0
							LUC	0	%		< 4.0
							INR-VALUE	0.95			0.83 - 1.43

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	010	1	SCREENING	-26	25JUN2009	9:45	aPTT	31.2	sec			26.0 - 40.0
						QUICK (VENOUS)	108	%			> 70	
			V1 (WEEK 0)	1	21JUL2009	11:00	ERYTHROCYTES	4	/pL	LOW	NCS	4.2 - 5.7
							HEMOGLOBIN	7.8	mmol/L	LOW	NCS	8.4 - 11.2
							HEMATOCRIT	0.41	L/L			0.39 - 0.55
							MCH (HbE)	1.97	fmol			1.74 - 1.99
							MCHC	19.3	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	102	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	206	/nL			150 - 400
							LEUKOCYTES	7.2	/nL			4.0 - 9.0
							NEUTROPHILS	57.3	%			50.0 - 70.0
							LYMPHOCYTES	29.6	%			25.0 - 40.0
							MONOCYTES	11.6	%			2.0 - 14.0
							EOSINOPHILS	1.1	%			< 4.0
							BASOPHILS	0.4	%			< 1.0
							LUC	0	%			< 4.0
			V3 (WEEK 12)	85	13OCT2009	10:45	ERYTHROCYTES	4	/pL	LOW	NCS	4.2 - 5.7
							HEMOGLOBIN	7.8	mmol/L	LOW	NCS	8.4 - 11.2
							HEMATOCRIT	0.4	L/L			0.39 - 0.55
							MCH (HbE)	1.97	fmol			1.74 - 1.99
							MCHC	19.8	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	99.2	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	220	/nL			150 - 400

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	010	1	V3 (WEEK 12)	85	13OCT2009	10:45	LEUKOCYTES	6	/nL		4.0 - 9.0
							NEUTROPHILS	51.2	%		50.0 - 70.0
							LYMPHOCYTES	35.5	%		25.0 - 40.0
							MONOCYTES	11.3	%		2.0 - 14.0
							EOSINOPHILS	1.7	%		< 4.0
							BASOPHILS	0.3	%		< 1.0
	012	1	SCREENING	-32	17JUN2010	12:20	ERYTHROCYTES	4.4	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.43	L/L		0.40 - 0.50
							MCH (HbE)	1.97	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	97.1	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	240	/nL		163 - 337
							LEUKOCYTES	6.5	/nL		4.2 - 9.1
							NEUTROPHILS	63.8	%		34.0 - 68.0
							LYMPHOCYTES	26.2	%		22.0 - 53.0
							MONOCYTES	8.6	%		5.0 - 12.0
							EOSINOPHILS	0.9	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
							INR-VALUE	1.04			0.83 - 1.43
							aPTT	33.2	sec		26.0 - 40.0
							QUICK (VENOUS)	94	%		> 70

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	012	1	V1 (WEEK 0)	1	19JUL2010	10:00	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.92	fmol		1.59 - 2.00
							MCHC	18.9	mmol/L	LOW NCS	19.8 - 22.3
							MCV	101.5	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	241	/nL		163 - 337
							LEUKOCYTES	6.1	/nL		4.2 - 9.1
							NEUTROPHILS	65.5	%		34.0 - 68.0
							LYMPHOCYTES	23.8	%		22.0 - 53.0
							MONOCYTES	8.7	%		5.0 - 12.0
							EOSINOPHILS	1.7	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
			V3 (WEEK 12)	88	14OCT2010	9:15	ERYTHROCYTES	4.5	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.43	L/L		0.40 - 0.50
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	20.1	mmol/L		19.8 - 22.3
							MCV	96.9	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	258	/nL		163 - 337
							LEUKOCYTES	6.5	/nL		4.2 - 9.1
							NEUTROPHILS	65	%		34.0 - 68.0
							LYMPHOCYTES	18.7	%	LOW NCS	22.0 - 53.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	012	1	V3 (WEEK 12)	88	14OCT2010	9:15	MONOCYTES	14.1	%	HIGH NCS	5.0 - 12.0
			V5 (WEEK 36)	257	01APR2011	9:30	EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
							ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	8.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	19.3	mmol/L	LOW NCS	19.8 - 22.3
							MCV	100.4	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	259	/nL		163 - 337
							LEUKOCYTES	4.7	/nL		4.2 - 9.1
							NEUTROPHILS	51.5	%		34.0 - 68.0
							LYMPHOCYTES	37.2	%		22.0 - 53.0
							MONOCYTES	9.8	%		5.0 - 12.0
							EOSINOPHILS	1.3	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V6 (WEEK 52)	361	14JUL2011	10:25	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	8.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	97	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	230	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	012	1	V6 (WEEK 52)	361	14JUL2011	10:25	LEUKOCYTES	5.5	/nL		4.2 - 9.1
							NEUTROPHILS	59.4	%		34.0 - 68.0
							LYMPHOCYTES	27.8	%		22.0 - 53.0
							MONOCYTES	10.5	%		5.0 - 12.0
							EOSINOPHILS	1.8	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
			V7 (WEEK 56)	396	18AUG2011	12:20	ERYTHROCYTES	4.2	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.2	mmol/L	LOW NCS	8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	18.8	mmol/L	LOW NCS	19.8 - 22.3
							MCV	102.8	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	212	/nL		163 - 337
							LEUKOCYTES	6.2	/nL		4.2 - 9.1
							NEUTROPHILS	66.8	%		34.0 - 68.0
							LYMPHOCYTES	22.1	%		22.0 - 53.0
							MONOCYTES	8.4	%		5.0 - 12.0
							EOSINOPHILS	2.4	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
	014	4	SCREENING	-26	07OCT2009	11:30	ERYTHROCYTES	4.7	/pL		4.2 - 5.7
							HEMOGLOBIN	8.9	mmol/L		8.4 - 11.2
							HEMATOCRIT	0.45	L/L		0.39 - 0.55

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	014	4	SCREENING	-26	07OCT2009	11:30	MCH (HbE)	1.9	fmol			1.74 - 1.99
							MCHC	19.7	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	96.6	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	198	/nL			150 - 400
							LEUKOCYTES	4.8	/nL			4.0 - 9.0
							NEUTROPHILS	51.2	%			50.0 - 70.0
							LYMPHOCYTES	38.4	%			25.0 - 40.0
							MONOCYTES	7.7	%			2.0 - 14.0
							EOSINOPHILS	2.3	%			< 4.0
							BASOPHILS	0.4	%			< 1.0
							INR-VALUE	1.07				0.83 - 1.43
							aPTT	40.2	sec	HIGH	NCS	26.0 - 40.0
							QUICK (VENOUS)	90	%			> 70
			V1 (WEEK 0)	1	02NOV2009	9:30	ERYTHROCYTES	4.9	/pL			4.2 - 5.7
							HEMOGLOBIN	9.4	mmol/L			8.4 - 11.2
							HEMATOCRIT	0.46	L/L			0.39 - 0.55
							MCH (HbE)	1.94	fmol			1.74 - 1.99
							MCHC	20.4	mmol/L			19.9 - 22.9
							MCV	95.3	fL			82.0 - 96.0
							THROMBOCYTES	182	/nL			150 - 400
							LEUKOCYTES	4.9	/nL			4.0 - 9.0
							NEUTROPHILS	51.7	%			50.0 - 70.0
							LYMPHOCYTES	37	%			25.0 - 40.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	014	4	V1 (WEEK 0)	1	02NOV2009	9:30	MONOCYTES	8	%		2.0 - 14.0
			V3 (WEEK 12)	85	25JAN2010	10:00	EOSINOPHILS	2.9	%		< 4.0
							BASOPHILS	0.4	%		< 1.0
							ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.97	fmol		1.59 - 2.00
							MCHC	21.5	mmol/L		19.8 - 22.3
							MCV	91.7	fL		79.0 - 92.2
							THROMBOCYTES	183	/nL		163 - 337
							LEUKOCYTES	5.1	/nL		4.2 - 9.1
							NEUTROPHILS	55.6	%		34.0 - 68.0
							LYMPHOCYTES	33.9	%		22.0 - 53.0
							MONOCYTES	7.8	%		5.0 - 12.0
							EOSINOPHILS	2.3	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V4 (WEEK 24)	172	22APR2010	10:15	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	20.1	mmol/L		19.8 - 22.3
							MCV	94.7	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	186	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range				
					Date	Time									
ACI-91	014	4	V4 (WEEK 24)	172	22APR2010	10:15	LEUKOCYTES	5.5	/nL		4.2 - 9.1				
							NEUTROPHILS	60.2	%		34.0 - 68.0				
							LYMPHOCYTES	29.6	%		22.0 - 53.0				
							MONOCYTES	7.1	%		5.0 - 12.0				
							EOSINOPHILS	2.7	%		1.0 - 7.0				
							BASOPHILS	0.4	%		< 1.0				
			V5 (WEEK 36)	256	15JUL2010	10:30	ERYTHROCYTES	4.6	/pL		4.6 - 6.1				
							HEMOGLOBIN	8.9	mmol/L		8.5 - 10.9				
							HEMATOCRIT	0.53	L/L	HIGH NCS	0.40 - 0.50				
							MCH (HbE)	1.93	fmol		1.59 - 2.00				
							MCHC	16.8	mmol/L	LOW NCS	19.8 - 22.3				
							MCV	114.9	fL	HIGH NCS	79.0 - 92.2				
							THROMBOCYTES	146	/nL	LOW NCS	163 - 337				
							LEUKOCYTES	4.5	/nL		4.2 - 9.1				
							NEUTROPHILS	51.9	%		34.0 - 68.0				
							LYMPHOCYTES	38.8	%		22.0 - 53.0				
							MONOCYTES	7.1	%		5.0 - 12.0				
							EOSINOPHILS	1.8	%		1.0 - 7.0				
							BASOPHILS	0.4	%		< 1.0				
							V6 (WEEK 52)	361	28OCT2010	11:00	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
											HEMOGLOBIN	9.2	mmol/L		8.5 - 10.9
			HEMATOCRIT	0.43	L/L						0.40 - 0.50				
			MCH (HbE)	1.96	fmol						1.59 - 2.00				

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	014	4	V6 (WEEK 52)	361	28OCT2010	11:00	MCHC	21.3	mmol/L		19.8 - 22.3
							MCV	91.9	fL		79.0 - 92.2
							THROMBOCYTES	163	/nL		163 - 337
							LEUKOCYTES	5.2	/nL		4.2 - 9.1
							NEUTROPHILS	59.4	%		34.0 - 68.0
							LYMPHOCYTES	30.1	%		22.0 - 53.0
							MONOCYTES	8.2	%		5.0 - 12.0
							EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V7 (WEEK 56)	396	02DEC2010	11:30	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.42	L/L		0.40 - 0.50
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	21.4	mmol/L		19.8 - 22.3
							MCV	91.2	fL		79.0 - 92.2
							THROMBOCYTES	179	/nL		163 - 337
							LEUKOCYTES	5.3	/nL		4.2 - 9.1
							NEUTROPHILS	61.5	%		34.0 - 68.0
							LYMPHOCYTES	27.8	%		22.0 - 53.0
							MONOCYTES	7.5	%		5.0 - 12.0
							EOSINOPHILS	2.8	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	015	4	SCREENING	-32	21JAN2010	10:30	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.97	fmol		1.59 - 2.00
							MCHC	20.4	mmol/L		19.8 - 22.3
							MCV	96.4	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	237	/nL		182 - 369
							LEUKOCYTES	6.3	/nL		4.0 - 10.0
							NEUTROPHILS	58.5	%		34.0 - 71.0
							LYMPHOCYTES	31	%		19.0 - 52.0
							MONOCYTES	8.2	%		5.0 - 13.0
							EOSINOPHILS	1.7	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
							INR-VALUE	1.02			0.83 - 1.43
							aPTT	37.5	sec		26.0 - 40.0
							QUICK (VENOUS)	97	%		> 70
			V1 (WEEK 0)	1	22FEB2010	9:00	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	9.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.92	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	93.6	fL		79.4 - 94.8
							THROMBOCYTES	221	/nL		182 - 369

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	015	4	V1 (WEEK 0)	1	22FEB2010	9:00	LEUKOCYTES	7.4	/nL		4.0 - 10.0
							NEUTROPHILS	71.7	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	18.9	%	LOW NCS	19.0 - 52.0
							MONOCYTES	5.3	%		5.0 - 13.0
							EOSINOPHILS	3.4	%		1.0 - 6.0
			V3 (WEEK 12)	85	17MAY2010	10:00	BASOPHILS	0.7	%		< 1.0
							ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	95.1	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	241	/nL		182 - 369
							LEUKOCYTES	6.3	/nL		4.0 - 10.0
							NEUTROPHILS	64.4	%		34.0 - 71.0
							LYMPHOCYTES	25.9	%		19.0 - 52.0
							MONOCYTES	6.7	%		5.0 - 13.0
							EOSINOPHILS	2.4	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
			V4 (WEEK 24)	162	02AUG2010	9:30	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	015	4	V4 (WEEK 24)	162	02AUG2010	9:30	MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	96.6	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	240	/nL		182 - 369
							LEUKOCYTES	6.3	/nL		4.0 - 10.0
							NEUTROPHILS	59.6	%		34.0 - 71.0
							LYMPHOCYTES	31.6	%		19.0 - 52.0
							MONOCYTES	6	%		5.0 - 13.0
							EOSINOPHILS	2.2	%		1.0 - 6.0
			V5 (WEEK 36)	248	27OCT2010	9:45	BASOPHILS	0.6	%		< 1.0
							ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.97	fmol		1.59 - 2.00
							MCHC	20.4	mmol/L		19.8 - 22.3
							MCV	96.8	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	247	/nL		182 - 369
							LEUKOCYTES	7.9	/nL		4.0 - 10.0
							NEUTROPHILS	64.6	%		34.0 - 71.0
							LYMPHOCYTES	27.1	%		19.0 - 52.0
							MONOCYTES	5.3	%		5.0 - 13.0
							EOSINOPHILS	2.4	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
			V6 (WEEK 52)	365	21FEB2011	10:30	ERYTHROCYTES		/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	015	4	V6 (WEEK 52)	365	21FEB2011	10:30	HEMOGLOBIN		mmol/L		6.9 - 9.7
							HEMATOCRIT		L/L		0.35 - 0.45
							MCH (HbE)		fmol		1.59 - 2.00
							MCHC		mmol/L		19.8 - 22.3
							MCV		fL		79.4 - 94.8
							THROMBOCYTES		/nL		182 - 369
							LEUKOCYTES		/nL		4.0 - 10.0
							NEUTROPHILS		%		34.0 - 71.0
							LYMPHOCYTES		%		19.0 - 52.0
							MONOCYTES		%		5.0 - 13.0
							EOSINOPHILS		%		1.0 - 6.0
							BASOPHILS		%		< 1.0
			V7 (WEEK 56)	394	22MAR2011	10:15	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	98.3	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	258	/nL		182 - 369
							LEUKOCYTES	10	/nL		4.0 - 10.0
							NEUTROPHILS	74.3	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	17.6	%	LOW NCS	19.0 - 52.0
							MONOCYTES	6.1	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	015	4	V7 (WEEK 56)	394	22MAR2011	10:15	EOSINOPHILS	1.7	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
	017	5	SCREENING	-22	14JUL2009	10:30	ERYTHROCYTES	4.4	/pL		4.2 - 5.7
							HEMOGLOBIN	8.8	mmol/L		8.4 - 11.2
							HEMATOCRIT	0.45	L/L		0.39 - 0.55
							MCH (HbE)	2	fmol	HIGH NCS	1.74 - 1.99
							MCHC	19.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	102.1	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	200	/nL		150 - 400
							LEUKOCYTES	6.8	/nL		4.0 - 9.0
							NEUTROPHILS	66.5	%		50.0 - 70.0
							LYMPHOCYTES	22.5	%	LOW NCS	25.0 - 40.0
							MONOCYTES	9.4	%		2.0 - 14.0
							EOSINOPHILS	1.2	%		< 4.0
							BASOPHILS	0.4	%		< 1.0
							LUC	0	%		< 4.0
							INR-VALUE	1.17			0.83 - 1.43
							aPTT	28.7	sec		26.0 - 40.0
							QUICK (VENOUS)	81	%		> 70
			V1 (WEEK 0)	1	05AUG2009	9:00	ERYTHROCYTES	4.2	/pL		4.2 - 5.7
							HEMOGLOBIN	8.6	mmol/L		8.4 - 11.2
							HEMATOCRIT	0.45	L/L		0.39 - 0.55

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	017	5	V1 (WEEK 0)	1	05AUG2009	9:00	MCH (HbE)	2.04	fmol	HIGH	NCS	1.74 - 1.99
							MCHC	19.2	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	106.4	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	231	/nL			150 - 400
							LEUKOCYTES	6.8	/nL			4.0 - 9.0
							NEUTROPHILS	64.2	%			50.0 - 70.0
							LYMPHOCYTES	21.9	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	11.8	%			2.0 - 14.0
							EOSINOPHILS	1.8	%			< 4.0
							BASOPHILS	0.3	%			< 1.0
			V3 (WEEK 12)	85	28OCT2009	8:45	ERYTHROCYTES	4.3	/pL			4.2 - 5.7
							HEMOGLOBIN	8.5	mmol/L			8.4 - 11.2
							HEMATOCRIT	0.42	L/L			0.39 - 0.55
							MCH (HbE)	1.99	fmol			1.74 - 1.99
							MCHC	20.2	mmol/L			19.9 - 22.9
							MCV	98.6	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	251	/nL			150 - 400
							LEUKOCYTES	6.2	/nL			
							NEUTROPHILS	61.8	%			50.0 - 70.0
							LYMPHOCYTES	23.8	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	12	%			2.0 - 14.0
							EOSINOPHILS	1.8	%			< 4.0
							BASOPHILS	0.6	%			< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	017	5	V4 (WEEK 24)	169	20JAN2010	9:00	ERYTHROCYTES	4.3	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.43	L/L			0.40 - 0.50
							MCH (HbE)	2	fmol			1.59 - 2.00
							MCHC	20.2	mmol/L			19.8 - 22.3
							MCV	99.3	fL			79.0 - 92.2
							THROMBOCYTES	217	/nL			163 - 337
							LEUKOCYTES	7	/nL			4.2 - 9.1
							NEUTROPHILS	56.3	%			34.0 - 68.0
							LYMPHOCYTES	23.5	%			22.0 - 53.0
			V5 (WEEK 36)	252	13APR2010	10:45	MONOCYTES	17.1	%	HIGH	NCS	5.0 - 12.0
							EOSINOPHILS	2.7	%			1.0 - 7.0
							BASOPHILS	0.4	%			< 1.0
							ERYTHROCYTES	4.6	/pL			4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.45	L/L			0.40 - 0.50
							MCH (HbE)	1.99	fmol			1.59 - 2.00
							MCHC	20.5	mmol/L			19.8 - 22.3
							MCV	97.2	fL			79.0 - 92.2
							THROMBOCYTES	230	/nL			163 - 337
							LEUKOCYTES	6.9	/nL			4.2 - 9.1
							NEUTROPHILS	60.3	%			34.0 - 68.0
							LYMPHOCYTES	26.3	%			22.0 - 53.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant range	
ACI-91	017	5	V5 (WEEK 36)	252	13APR2010	10:45	MONOCYTES	11.5	%		5.0 - 12.0
			V6 (WEEK 52)	364	03AUG2010	9:00	EOSINOPHILS	1.3	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
							ERYTHROCYTES	4.3	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	2.01	fmol	HIGH NCS	1.59 - 2.00
							MCHC	19.7	mmol/L	LOW NCS	19.8 - 22.3
							MCV	101.9	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	342	/nL	HIGH NCS	163 - 337
							LEUKOCYTES	8.8	/nL		4.2 - 9.1
							NEUTROPHILS	66.7	%		34.0 - 68.0
							LYMPHOCYTES	22.3	%		22.0 - 53.0
							MONOCYTES	8.8	%		5.0 - 12.0
							EOSINOPHILS	1.7	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
			V7 (WEEK 56)	392	31AUG2010	9:00	ERYTHROCYTES	4.4	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.43	L/L		0.40 - 0.50
							MCH (HbE)	2.05	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.7	mmol/L		19.8 - 22.3
							MCV	99.1	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	240	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	017	5	V7 (WEEK 56)	392	31AUG2010	9:00	LEUKOCYTES	8	/nL		4.2 - 9.1
							NEUTROPHILS	55.5	%		34.0 - 68.0
							LYMPHOCYTES	30.3	%		22.0 - 53.0
							MONOCYTES	12.2	%	HIGH NCS	5.0 - 12.0
							EOSINOPHILS	1.6	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
	019	5	SCREENING	-21	18NOV2009	13:00	ERYTHROCYTES	4.5	/pL		4.2 - 5.7
							HEMOGLOBIN	8.9	mmol/L		8.4 - 11.2
							HEMATOCRIT	0.44	L/L		0.39 - 0.55
							MCH (HbE)	2	fmol	HIGH NCS	1.74 - 1.99
							MCHC	20.3	mmol/L		19.9 - 22.9
							MCV	98.4	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	164	/nL		150 - 400
							LEUKOCYTES	5	/nL		4.0 - 9.0
							NEUTROPHILS	52.6	%		50.0 - 70.0
							LYMPHOCYTES	34.9	%		25.0 - 40.0
							MONOCYTES	8.9	%		2.0 - 14.0
							EOSINOPHILS	3.4	%		< 4.0
							BASOPHILS	0.2	%		< 1.0
							INR-VALUE	1.23			0.83 - 1.43
							aPTT	40.7	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	73	%		> 70

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
ACI-91	019	5	V1 (WEEK 0)	1	09DEC2009	9:00	ERYTHROCYTES	4.5	/pL			4.2 - 5.7
							HEMOGLOBIN	9	mmol/L			8.4 - 11.2
							HEMATOCRIT	0.46	L/L			0.39 - 0.55
							MCH (HbE)	1.99	fmol			1.74 - 1.99
							MCHC	19.7	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	101.1	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	201	/nL			150 - 400
							LEUKOCYTES	7.3	/nL			4.0 - 9.0
							NEUTROPHILS	58.8	%			50.0 - 70.0
							LYMPHOCYTES	29.3	%			25.0 - 40.0
							MONOCYTES	8.7	%			2.0 - 14.0
							EOSINOPHILS	2.9	%			< 4.0
							BASOPHILS	0.3	%			< 1.0
			V3 (WEEK 12)	85	03MAR2010	9:00	ERYTHROCYTES	4.6	/pL			4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.44	L/L			0.40 - 0.50
							MCH (HbE)	2.03	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	20.8	mmol/L			19.8 - 22.3
							MCV	97.4	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	182	/nL			163 - 337
							LEUKOCYTES	5.5	/nL			4.2 - 9.1
							NEUTROPHILS	53.6	%			34.0 - 68.0
							LYMPHOCYTES	32.5	%			22.0 - 53.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	019	5	V3 (WEEK 12)	85	03MAR2010	9:00	MONOCYTES	9.5	%		5.0 - 12.0
							EOSINOPHILS	4	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V4 (WEEK 24)	168	25MAY2010	9:00	ERYTHROCYTES	4.5	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	2.06	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.9	mmol/L		19.8 - 22.3
							MCV	98.7	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	186	/nL		163 - 337
							LEUKOCYTES	5.7	/nL		4.2 - 9.1
							NEUTROPHILS	57.5	%		34.0 - 68.0
							LYMPHOCYTES	28.3	%		22.0 - 53.0
							MONOCYTES	10.8	%		5.0 - 12.0
							EOSINOPHILS	3	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V5 (WEEK 36)	259	24AUG2010	12:00	ERYTHROCYTES	4.4	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.98	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	99.1	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	220	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	019	5	V5 (WEEK 36)	259	24AUG2010	12:00	LEUKOCYTES	6.4	/nL			4.2 - 9.1
							NEUTROPHILS	67.8	%			34.0 - 68.0
							LYMPHOCYTES	21.4	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	9.3	%			5.0 - 12.0
							EOSINOPHILS	1.3	%			1.0 - 7.0
			V6 (WEEK 52)	364	07DEC2010	13:30	BASOPHILS	0.2	%			< 1.0
							ERYTHROCYTES	4.7	/pL			4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.46	L/L			0.40 - 0.50
							MCH (HbE)	1.98	fmol			1.59 - 2.00
							MCHC	20.5	mmol/L			19.8 - 22.3
							MCV	96.8	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	190	/nL			163 - 337
							LEUKOCYTES	5.1	/nL			4.2 - 9.1
							NEUTROPHILS	59	%			34.0 - 68.0
							LYMPHOCYTES	26.5	%			22.0 - 53.0
							MONOCYTES	8.4	%			5.0 - 12.0
							EOSINOPHILS	5.7	%			1.0 - 7.0
							BASOPHILS	0.4	%			< 1.0
			V7 (WEEK 56)	399	11JAN2011	9:10	ERYTHROCYTES	4.6	/pL			4.6 - 6.1
							HEMOGLOBIN	9.3	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.44	L/L			0.40 - 0.50
							MCH (HbE)	2.03	fmol	HIGH	NCS	1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	019	5	V7 (WEEK 56)	399	11JAN2011	9:10	MCHC	21	mmol/L		19.8 - 22.3
							MCV	96.5	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	182	/nL		163 - 337
							LEUKOCYTES	5.6	/nL		4.2 - 9.1
							NEUTROPHILS	58.9	%		34.0 - 68.0
							LYMPHOCYTES	26.3	%		22.0 - 53.0
							MONOCYTES	9.4	%		5.0 - 12.0
							EOSINOPHILS	5	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
	023	4	SCREENING	-19	01JUL2010	11:00	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	9.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.48	L/L		0.40 - 0.50
							MCH (HbE)	2.03	fmol	HIGH NCS	1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	102.3	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	182	/nL		163 - 337
							LEUKOCYTES	5.3	/nL		4.2 - 9.1
							NEUTROPHILS	57.7	%		34.0 - 68.0
							LYMPHOCYTES	33	%		22.0 - 53.0
							MONOCYTES	6.6	%		5.0 - 12.0
							EOSINOPHILS	2.1	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range					
					Date	Time										
ACI-91	023	4	SCREENING	-19	01JUL2010	11:00	INR-VALUE	1.02			0.83 - 1.43					
							aPTT	34	sec		26.0 - 40.0					
							QUICK (VENOUS)	97	%		> 70					
			V1 (WEEK 0)	1	20JUL2010	10:00	ERYTHROCYTES	4.8	/pL			4.6 - 6.1				
							HEMOGLOBIN	9.8	mmol/L			8.5 - 10.9				
							HEMATOCRIT	0.51	L/L	HIGH	NCS	0.40 - 0.50				
							MCH (HbE)	2.04	fmol	HIGH	NCS	1.59 - 2.00				
							MCHC	19.2	mmol/L	LOW	NCS	19.8 - 22.3				
							MCV	106	fL	HIGH	NCS	79.0 - 92.2				
							THROMBOCYTES	187	/nL			163 - 337				
							LEUKOCYTES	4.1	/nL	LOW	NCS	4.2 - 9.1				
							NEUTROPHILS	61.7	%			34.0 - 68.0				
							LYMPHOCYTES	27.7	%			22.0 - 53.0				
							MONOCYTES	8	%			5.0 - 12.0				
							EOSINOPHILS	1.9	%			1.0 - 7.0				
							BASOPHILS	0.7	%			< 1.0				
							V3 (WEEK 12)	86	13OCT2010	9:30	ERYTHROCYTES	4.8	/pL			4.6 - 6.1
											HEMOGLOBIN	9.7	mmol/L			8.5 - 10.9
											HEMATOCRIT	0.46	L/L			0.40 - 0.50
											MCH (HbE)	2.03	fmol	HIGH	NCS	1.59 - 2.00
			MCHC	21.3	mmol/L							19.8 - 22.3				
			MCV	95.4	fL	HIGH					NCS	79.0 - 92.2				
			THROMBOCYTES	213	/nL			163 - 337								

Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	023	4	V3 (WEEK 12)	86	13OCT2010	9:30	LEUKOCYTES	5.2	/nL		4.2 - 9.1
							NEUTROPHILS	66.1	%		34.0 - 68.0
							LYMPHOCYTES	23.7	%		22.0 - 53.0
							MONOCYTES	8.3	%		5.0 - 12.0
							EOSINOPHILS	1.3	%		1.0 - 7.0
			V4 (WEEK 24)	177	12JAN2011	10:30	BASOPHILS	0.6	%		< 1.0
							ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	2.03	fmol	HIGH NCS	1.59 - 2.00
							MCHC	21.3	mmol/L		19.8 - 22.3
							MCV	95.3	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	202	/nL		163 - 337
							LEUKOCYTES	5.1	/nL		4.2 - 9.1
							NEUTROPHILS	63.5	%		34.0 - 68.0
							LYMPHOCYTES	24.1	%		22.0 - 53.0
							MONOCYTES	10.6	%		5.0 - 12.0
							EOSINOPHILS	1.4	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V5 (WEEK 36)	245	21MAR2011	9:45	ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	10	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	2	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	023	4	V5 (WEEK 36)	245	21MAR2011	9:45	MCHC	21.2	mmol/L		19.8 - 22.3
							MCV	94.6	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	213	/nL		163 - 337
							LEUKOCYTES	6.4	/nL		4.2 - 9.1
							NEUTROPHILS	70.4	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	21.5	%	LOW NCS	22.0 - 53.0
							MONOCYTES	7.4	%		5.0 - 12.0
							EOSINOPHILS	0.5	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V6 (WEEK 52)	364	18JUL2011	10:00	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	2	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	95.5	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	211	/nL		163 - 337
							LEUKOCYTES	5.2	/nL		4.2 - 9.1
							NEUTROPHILS	66.6	%		34.0 - 68.0
							LYMPHOCYTES	22.5	%		22.0 - 53.0
							MONOCYTES	9.7	%		5.0 - 12.0
							EOSINOPHILS	1	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V7 (WEEK 56)	388	11AUG2011	11:15	ERYTHROCYTES	5	/pL		4.6 - 6.1

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	023	4	V7 (WEEK 56)	388	11AUG2011	11:15	HEMOGLOBIN	9.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.5	L/L		0.40 - 0.50
							MCH (HbE)	2	fmol		1.59 - 2.00
							MCHC	19.9	mmol/L		19.8 - 22.3
							MCV	100.6	fL	HIGH	79.0 - 92.2
							THROMBOCYTES	232	/nL		163 - 337
							LEUKOCYTES	6	/nL		4.2 - 9.1
							NEUTROPHILS	66.4	%		34.0 - 68.0
							LYMPHOCYTES	23.1	%		22.0 - 53.0
							MONOCYTES	9.2	%		5.0 - 12.0
							EOSINOPHILS	1	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
							ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	9	mmol/L		6.9 - 9.7
	027	20	SCREENING	-21	30SEP2010	10:35	HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	2.06	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	100.9	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	261	/nL		182 - 369
							LEUKOCYTES	17.2	/nL	HIGH CS	4.0 - 10.0
							NEUTROPHILS	78	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	13	%	LOW NCS	19.0 - 52.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.	
					Date	Time				High signi- /Low	ficant Reference range
ACI-91	027	20	SCREENING	-21	30SEP2010	10:35	MONOCYTES	7.1	%		5.0 - 13.0
							EOSINOPHILS	1.6	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
							INR-VALUE				0.83 - 1.43
							aPTT		sec		26.0 - 40.0
			V1 (WEEK 0)	1	21OCT2010	9:15	QUICK (VENOUS)		%		> 70
							ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	2.07	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	100.7	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	321	/nL		182 - 369
							LEUKOCYTES	15.9	/nL	HIGH CS	4.0 - 10.0
							NEUTROPHILS	73.5	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	14.2	%	LOW NCS	19.0 - 52.0
							MONOCYTES	9	%		5.0 - 13.0
							EOSINOPHILS	2.4	%		1.0 - 6.0
							BASOPHILS	0.9	%		< 1.0
			V3 (WEEK 12)	92	20JAN2011	10:55	ERYTHROCYTES	4.1	/pL		3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	2.03	fmol	HIGH NCS	1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	027	20	V3 (WEEK 12)	92	20JAN2011	10:55	MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	101	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	310	/nL		182 - 369
							LEUKOCYTES	13.8	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	78.8	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	12.6	%	LOW NCS	19.0 - 52.0
							MONOCYTES	6.7	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V4 (WEEK 24)	174	12APR2011	10:30	ERYTHROCYTES	4.3	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	2.12	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.7	mmol/L		19.8 - 22.3
							MCV	102.3	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	293	/nL		182 - 369
							LEUKOCYTES	12.3	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	70.7	%		34.0 - 71.0
							LYMPHOCYTES	19.2	%		19.0 - 52.0
							MONOCYTES	7.7	%		5.0 - 13.0
							EOSINOPHILS	1.7	%		1.0 - 6.0
							BASOPHILS	0.7	%		< 1.0
			V5 (WEEK 36)	259	06JUL2011	10:55	ERYTHROCYTES	4.2	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
ACI-91	027	20	V5 (WEEK 36)	259	06JUL2011	10:55	HEMOGLOBIN	8.6	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.45	L/L			0.35 - 0.45
							MCH (HbE)	2.05	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	19.3	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	106	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	260	/nL			182 - 369
							LEUKOCYTES	13.3	/nL	HIGH	NCS	4.0 - 10.0
							NEUTROPHILS	71.9	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	16.3	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	8.6	%			5.0 - 13.0
							EOSINOPHILS	2.6	%			1.0 - 6.0
							BASOPHILS	0.6	%			< 1.0
			V6 (WEEK 52)	370	25OCT2011	8:19	ERYTHROCYTES	4.5	/pL			3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.45	L/L			0.35 - 0.45
							MCH (HbE)	2.06	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	20.4	mmol/L			19.8 - 22.3
							MCV	100.9	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	286	/nL			182 - 369
							LEUKOCYTES	18.2	/nL	HIGH	NCS	4.0 - 10.0
							NEUTROPHILS	78.3	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	12.7	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	6.3	%			5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	027	20	V6 (WEEK 52)	370	25OCT2011	8:19	EOSINOPHILS	2.4	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V7 (WEEK 56)	407	01DEC2011	10:10	ERYTHROCYTES	4.1	/pL		3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	2.03	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	99.5	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	399	/nL	HIGH NCS	182 - 369
							LEUKOCYTES	16.4	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	80.8	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	12.3	%	LOW NCS	19.0 - 52.0
							MONOCYTES	5.3	%		5.0 - 13.0
							EOSINOPHILS	1.1	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
	030	8	SCREENING	-7	18MAR2010	10:30	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.94	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	95.6	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	261	/nL		182 - 369

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	030	8	SCREENING	-7	18MAR2010	10:30	LEUKOCYTES	7	/nL		4.0 - 10.0
							NEUTROPHILS	62.5	%		34.0 - 71.0
							LYMPHOCYTES	28.2	%		19.0 - 52.0
							MONOCYTES	6.5	%		5.0 - 13.0
							EOSINOPHILS	2.4	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	1.1			0.83 - 1.43
							aPTT	44.1	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	86	%		> 70
			V1 (WEEK 0)	1	25MAR2010	10:20	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.99	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	96.8	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	257	/nL		182 - 369
							LEUKOCYTES	6.6	/nL		4.0 - 10.0
							NEUTROPHILS	63.7	%		34.0 - 71.0
							LYMPHOCYTES	27.6	%		19.0 - 52.0
							MONOCYTES	5.9	%		5.0 - 13.0
							EOSINOPHILS	2.3	%		1.0 - 6.0
			V3 (WEEK 12)	85	17JUN2010	11:50	BASOPHILS	0.5	%		< 1.0
							ERYTHROCYTES	4.8	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	030	8	V3 (WEEK 12)	85	17JUN2010	11:50	HEMOGLOBIN	9.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	97.1	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	237	/nL		182 - 369
							LEUKOCYTES	6.4	/nL		4.0 - 10.0
							NEUTROPHILS	56.6	%		34.0 - 71.0
							LYMPHOCYTES	33.3	%		19.0 - 52.0
							MONOCYTES	7.6	%		5.0 - 13.0
							EOSINOPHILS	2	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V4 (WEEK 24)	163	03SEP2010	12:30	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.97	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	95.7	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	261	/nL		182 - 369
							LEUKOCYTES	7.6	/nL		4.0 - 10.0
							NEUTROPHILS	68.5	%		34.0 - 71.0
							LYMPHOCYTES	24.7	%		19.0 - 52.0
							MONOCYTES	5.4	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	030	8	V4 (WEEK 24)	163	03SEP2010	12:30	EOSINOPHILS	0.9	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0
			V5 (WEEK 36)	253	02DEC2010	12:50	ERYTHROCYTES	5	/pL			3.9 - 5.2
							HEMOGLOBIN	9.8	mmol/L	HIGH	NCS	6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.97	fmol			1.59 - 2.00
							MCHC	21.5	mmol/L			19.8 - 22.3
							MCV	91.4	fL			79.4 - 94.8
							THROMBOCYTES	245	/nL			182 - 369
							LEUKOCYTES	6.6	/nL			4.0 - 10.0
							NEUTROPHILS	47.9	%			34.0 - 71.0
							LYMPHOCYTES	41.4	%			19.0 - 52.0
							MONOCYTES	7.3	%			5.0 - 13.0
							EOSINOPHILS	2.3	%			1.0 - 6.0
							BASOPHILS	1.1	%	HIGH	NCS	< 1.0
			V6 (WEEK 52)	355	14MAR2011	11:00	ERYTHROCYTES	4.8	/pL			3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.97	fmol			1.59 - 2.00
							MCHC	20.3	mmol/L			19.8 - 22.3
							MCV	96.7	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	281	/nL			182 - 369
							LEUKOCYTES	8.5	/nL			4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	030	8	V6 (WEEK 52)	355	14MAR2011	11:00	NEUTROPHILS	67.8	%		34.0 - 71.0
							LYMPHOCYTES	24	%		19.0 - 52.0
							MONOCYTES	6.7	%		5.0 - 13.0
							EOSINOPHILS	1.1	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
			V7 (WEEK 56)	383	11APR2011	11:30	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9.9	mmol/L	HIGH NCS	6.9 - 9.7
							HEMATOCRIT	0.51	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	100	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	329	/nL		182 - 369
							LEUKOCYTES	8.4	/nL		4.0 - 10.0
							NEUTROPHILS	61.1	%		34.0 - 71.0
							LYMPHOCYTES	29.3	%		19.0 - 52.0
							MONOCYTES	7	%		5.0 - 13.0
							EOSINOPHILS	1.9	%		1.0 - 6.0
							BASOPHILS	0.7	%		< 1.0
	032	8	SCREENING	-10	08NOV2010	10:00	ERYTHROCYTES	4.1	/pL		3.9 - 5.2
							HEMOGLOBIN	7.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.37	L/L		0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	032	8	SCREENING	-10	08NOV2010	10:00	MCHC	21.4	mmol/L			19.8 - 22.3
							MCV	91.2	fL			79.4 - 94.8
							THROMBOCYTES	212	/nL			182 - 369
							LEUKOCYTES	5.4	/nL			4.0 - 10.0
							NEUTROPHILS	63.2	%			34.0 - 71.0
							LYMPHOCYTES	28.8	%			19.0 - 52.0
							MONOCYTES	7.2	%			5.0 - 13.0
							EOSINOPHILS	0.4	%	LOW	CS	1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0
							INR-VALUE	1.1				0.83 - 1.43
							aPTT	38.2	sec			26.0 - 40.0
							QUICK (VENOUS)	86	%			> 70
			V1 (WEEK 0)	1	18NOV2010	10:10	ERYTHROCYTES	4.4	/pL			3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.43	L/L			0.35 - 0.45
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	18.9	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	97.7	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	208	/nL			182 - 369
							LEUKOCYTES	5.2	/nL			4.0 - 10.0
							NEUTROPHILS	62.1	%			34.0 - 71.0
							LYMPHOCYTES	29.1	%			19.0 - 52.0
							MONOCYTES	7.8	%			5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	032	8	V1 (WEEK 0)	1	18NOV2010	10:10	EOSINOPHILS	0.6	%	LOW	CS	1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0
		V3 (WEEK 12)		82	07FEB2011	12:23	ERYTHROCYTES	4.4	/pL			3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.41	L/L			0.35 - 0.45
							MCH (HbE)	1.88	fmol			1.59 - 2.00
							MCHC	20.2	mmol/L			19.8 - 22.3
							MCV	93.2	fL			79.4 - 94.8
							THROMBOCYTES	204	/nL			182 - 369
							LEUKOCYTES	6	/nL			4.0 - 10.0
							NEUTROPHILS	53.1	%			34.0 - 71.0
							LYMPHOCYTES	36.8	%			19.0 - 52.0
							MONOCYTES	9.1	%			5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW	CS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
	033	9	SCREENING	-7	28OCT2009	8:15	ERYTHROCYTES	4.8	/pL			3.8 - 5.3
							HEMOGLOBIN	8.6	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.43	L/L			0.35 - 0.47
							MCH (HbE)	1.79	fmol			1.74 - 1.99
							MCHC	20	mmol/L			19.9 - 22.9
							MCV	89.6	fL			82.0 - 96.0
							THROMBOCYTES	329	/nL			150 - 400

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	033	9	SCREENING	-7	28OCT2009	8:15	LEUKOCYTES	5.9	/nL			4.0 - 9.0
							NEUTROPHILS	66.9	%			50.0 - 70.0
							LYMPHOCYTES	24.2	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	6.8	%			2.0 - 14.0
							EOSINOPHILS	1.9	%			< 4.0
							BASOPHILS	0.2	%			< 1.0
							INR-VALUE	0.91				0.83 - 1.43
							aPTT	46.9	sec	HIGH	NCS	26.0 - 40.0
							QUICK (VENOUS)	118	%			> 70
			V1 (WEEK 0)	1	04NOV2009	8:00	ERYTHROCYTES	4.6	/pL			3.8 - 5.3
							HEMOGLOBIN	8.2	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.42	L/L			0.35 - 0.47
							MCH (HbE)	1.78	fmol			1.74 - 1.99
							MCHC	19.5	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	90.9	fL			82.0 - 96.0
							THROMBOCYTES	299	/nL			150 - 400
							LEUKOCYTES	5.7	/nL			4.0 - 9.0
							NEUTROPHILS	66.7	%			50.0 - 70.0
							LYMPHOCYTES	26.2	%			25.0 - 40.0
							MONOCYTES	5.1	%			2.0 - 14.0
							EOSINOPHILS	1.7	%			< 4.0
			V3 (WEEK 12)	78	20JAN2010	9:05	BASOPHILS	0.3	%			< 1.0
							ERYTHROCYTES	4.7	/pL			3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	033	9	V3 (WEEK 12)	78	20JAN2010	9:05	HEMOGLOBIN	8.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	87.8	fL		79.4 - 94.8
							THROMBOCYTES	277	/nL		182 - 369
							LEUKOCYTES	5.5	/nL		4.0 - 10.0
							NEUTROPHILS	63.7	%		34.0 - 71.0
							LYMPHOCYTES	25.4	%		19.0 - 52.0
							MONOCYTES	7.3	%		5.0 - 13.0
							EOSINOPHILS	3.1	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
		V4 (WEEK 24)		169	21APR2010	9:30	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	89	fL		79.4 - 94.8
							THROMBOCYTES	320	/nL		182 - 369
							LEUKOCYTES	5.6	/nL		4.0 - 10.0
							NEUTROPHILS	66.8	%		34.0 - 71.0
							LYMPHOCYTES	24.7	%		19.0 - 52.0
							MONOCYTES	6.3	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	033	9	V4 (WEEK 24)	169	21APR2010	9:30	EOSINOPHILS	2	%			1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
			V5 (WEEK 36)	261	22JUL2010	8:30	ERYTHROCYTES	4.6	/pL			3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.79	fmol			1.59 - 2.00
							MCHC	18.8	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	94.8	fL			79.4 - 94.8
							THROMBOCYTES	276	/nL			182 - 369
							LEUKOCYTES	5.8	/nL			4.0 - 10.0
							NEUTROPHILS	67	%			34.0 - 71.0
							LYMPHOCYTES	25.7	%			19.0 - 52.0
							MONOCYTES	4.7	%	LOW	NCS	5.0 - 13.0
							EOSINOPHILS	2.4	%			1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
			V6 (WEEK 52)	372	10NOV2010	8:30	ERYTHROCYTES	5	/pL			3.9 - 5.2
							HEMOGLOBIN	9	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.43	L/L			0.35 - 0.45
							MCH (HbE)	1.79	fmol			1.59 - 2.00
							MCHC	20.7	mmol/L			19.8 - 22.3
							MCV	86.6	fL			79.4 - 94.8
							THROMBOCYTES	283	/nL			182 - 369
							LEUKOCYTES	4.3	/nL			4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	033	9	V6 (WEEK 52)	372	10NOV2010	8:30	NEUTROPHILS	65.8	%		34.0 - 71.0
							LYMPHOCYTES	22.1	%		19.0 - 52.0
							MONOCYTES	9.8	%		5.0 - 13.0
							EOSINOPHILS	2.3	%		1.0 - 6.0
							BASOPHILS	0	%		< 1.0
			V7 (WEEK 56)	398	06DEC2010	8:45	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.42	L/L		0.35 - 0.45
							MCH (HbE)	1.77	fmol		1.59 - 2.00
							MCHC	20.1	mmol/L		19.8 - 22.3
							MCV	87.9	fL		79.4 - 94.8
							THROMBOCYTES	316	/nL		182 - 369
							LEUKOCYTES	6	/nL		4.0 - 10.0
							NEUTROPHILS	59.4	%		34.0 - 71.0
							LYMPHOCYTES	29.5	%		19.0 - 52.0
							MONOCYTES	7.4	%		5.0 - 13.0
							EOSINOPHILS	3.4	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
	042	12	SCREENING	-29	16DEC2009	9:30	ERYTHROCYTES	5.1	/pL		3.8 - 5.3
							HEMOGLOBIN	9.4	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.46	L/L		0.35 - 0.47
							MCH (HbE)	1.84	fmol		1.74 - 1.99

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	042	12	SCREENING	-29	16DEC2009	9:30	MCHC	20.2	mmol/L		19.9 - 22.9
							MCV	91.2	fL		82.0 - 96.0
							THROMBOCYTES	217	/nL		150 - 400
							LEUKOCYTES	7.9	/nL		4.0 - 9.0
							NEUTROPHILS	64.3	%		50.0 - 70.0
							LYMPHOCYTES	22.3	%	LOW NCS	25.0 - 40.0
							MONOCYTES	10	%		2.0 - 14.0
							EOSINOPHILS	2.5	%		< 4.0
							BASOPHILS	0.9	%		< 1.0
							INR-VALUE	1.1			0.83 - 1.43
							aPTT	42.2	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	86	%		> 70
			V1 (WEEK 0)	1	14JAN2010	9:15	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	89.9	fL		79.4 - 94.8
							THROMBOCYTES	221	/nL		182 - 369
							LEUKOCYTES	7.3	/nL		4.0 - 10.0
							NEUTROPHILS	67.8	%		34.0 - 71.0
							LYMPHOCYTES	20.9	%		19.0 - 52.0
							MONOCYTES	8.8	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	042	12	V1 (WEEK 0)	1	14JAN2010	9:15	EOSINOPHILS	1.7	%			1.0 - 6.0
							BASOPHILS	0.8	%			< 1.0
			V3 (WEEK 12)	126	19MAY2010	8:30	ERYTHROCYTES	5.2	/pL			3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.58	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	16.4	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	112.8	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	228	/nL			182 - 369
							LEUKOCYTES	7.6	/nL			4.0 - 10.0
							NEUTROPHILS	67.1	%			34.0 - 71.0
							LYMPHOCYTES	20.4	%			19.0 - 52.0
							MONOCYTES	9.6	%			5.0 - 13.0
							EOSINOPHILS	2	%			1.0 - 6.0
							BASOPHILS	0.9	%			< 1.0
			V4 (WEEK 24)	168	30JUN2010	8:45	ERYTHROCYTES	4.8	/pL			3.9 - 5.2
							HEMOGLOBIN	8.5	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.76	fmol			1.59 - 2.00
							MCHC	18.5	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	95.2	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	178	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	7.3	/nL			4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	042	12	V4 (WEEK 24)	168	30JUN2010	8:45	NEUTROPHILS	63.7	%		34.0 - 71.0
							LYMPHOCYTES	24.5	%		19.0 - 52.0
							MONOCYTES	8.5	%		5.0 - 13.0
							EOSINOPHILS	2.2	%		1.0 - 6.0
							BASOPHILS	1.1	%	HIGH NCS	< 1.0
			V5 (WEEK 36)	252	22SEP2010	8:30	ERYTHROCYTES	5.8	/pL	HIGH NCS	3.9 - 5.2
							HEMOGLOBIN	10.3	mmol/L	HIGH NCS	6.9 - 9.7
							HEMATOCRIT	0.53	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	91.5	fL		79.4 - 94.8
							THROMBOCYTES	304	/nL		182 - 369
							LEUKOCYTES	7.9	/nL		4.0 - 10.0
							NEUTROPHILS	64.9	%		34.0 - 71.0
							LYMPHOCYTES	22.8	%		19.0 - 52.0
							MONOCYTES	9.3	%		5.0 - 13.0
							EOSINOPHILS	1.6	%		1.0 - 6.0
							BASOPHILS	1.4	%	HIGH NCS	< 1.0
			V6 (WEEK 52)	364	12JAN2011	8:30	ERYTHROCYTES	5.3	/pL	HIGH NCS	3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	20.1	mmol/L		19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	042	12	V6 (WEEK 52)	364	12JAN2011	8:30	MCV	89.6	fL		79.4 - 94.8
							THROMBOCYTES	270	/nL		182 - 369
							LEUKOCYTES	7.5	/nL		4.0 - 10.0
							NEUTROPHILS	66.4	%		34.0 - 71.0
							LYMPHOCYTES	22.4	%		19.0 - 52.0
							MONOCYTES	7.2	%		5.0 - 13.0
							EOSINOPHILS	2.9	%		1.0 - 6.0
							BASOPHILS	1.1	%	HIGH NCS	< 1.0
			V7 (WEEK 56)	391	08FEB2011	8:40	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.77	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	89.3	fL		79.4 - 94.8
							THROMBOCYTES	282	/nL		182 - 369
							LEUKOCYTES	7.1	/nL		4.0 - 10.0
							NEUTROPHILS	72	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	17.4	%	LOW NCS	19.0 - 52.0
							MONOCYTES	7.1	%		5.0 - 13.0
							EOSINOPHILS	2.5	%		1.0 - 6.0
							BASOPHILS	1	%	HIGH NCS	< 1.0
	043	12	SCREENING	-28	21OCT2009	9:45	ERYTHROCYTES	5.2	/pL		4.2 - 5.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
ACI-91	043	12	SCREENING	-28	21OCT2009	9:45	HEMOGLOBIN	10	mmol/L			8.4 - 11.2
							HEMATOCRIT	0.5	L/L			0.39 - 0.55
							MCH (HbE)	1.9	fmol			1.74 - 1.99
							MCHC	19.9	mmol/L			19.9 - 22.9
							MCV	95.6	fL			82.0 - 96.0
							THROMBOCYTES	305	/nL			150 - 400
							LEUKOCYTES	7.1	/nL			4.0 - 9.0
							NEUTROPHILS	69.1	%			50.0 - 70.0
							LYMPHOCYTES	22.8	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	6.4	%			2.0 - 14.0
							EOSINOPHILS	1.4	%			< 4.0
							BASOPHILS	0.3	%			< 1.0
							INR-VALUE	1.13				0.83 - 1.43
							aPTT	39.6	sec			26.0 - 40.0
							QUICK (VENOUS)	83	%			> 70
			V1 (WEEK 0)	1	18NOV2009	9:30	ERYTHROCYTES	5.2	/pL			4.2 - 5.7
							HEMOGLOBIN	10	mmol/L			8.4 - 11.2
							HEMATOCRIT	0.49	L/L			0.39 - 0.55
							MCH (HbE)	1.91	fmol			1.74 - 1.99
							MCHC	20.4	mmol/L			19.9 - 22.9
							MCV	93.9	fL			82.0 - 96.0
							THROMBOCYTES	308	/nL			150 - 400
							LEUKOCYTES	6.5	/nL			4.0 - 9.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	043	12	V1 (WEEK 0)	1	18NOV2009	9:30	NEUTROPHILS	70.1	%	HIGH	NCS	50.0 - 70.0
							LYMPHOCYTES	21.4	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	7.7	%			2.0 - 14.0
							EOSINOPHILS	0.6	%			< 4.0
							BASOPHILS	0.2	%			< 1.0
			V3 (WEEK 12)	85	10FEB2010	9:30	ERYTHROCYTES	5	/pL			4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.48	L/L			0.40 - 0.50
							MCH (HbE)	1.88	fmol			1.59 - 2.00
							MCHC	20	mmol/L			19.8 - 22.3
			V4 (WEEK 24)	176	12MAY2010	9:00	MCV	94.2	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	359	/nL	HIGH	NCS	163 - 337
							LEUKOCYTES	7.6	/nL			4.2 - 9.1
							NEUTROPHILS	79.8	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	12.2	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	7.2	%			5.0 - 12.0
							EOSINOPHILS	0.5	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.3	%			< 1.0
							LEUKOCYTES		/nL			4.2 - 9.1
	046	11	SCREENING	-28	14DEC2009	9:30	ERYTHROCYTES	5.1	/pL			3.8 - 5.3
							HEMOGLOBIN	10.2	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.5	L/L			0.35 - 0.47

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High signi- /Low	ficant	
ACI-91	046	11	SCREENING	-28	14DEC2009	9:30	MCH (HbE)	2	fmol	HIGH	NCS	1.74 - 1.99
							MCHC	20.3	mmol/L			19.9 - 22.9
							MCV	98.2	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	202	/nL			150 - 400
							LEUKOCYTES	5	/nL	HIGH	NCS	4.0 - 9.0
							NEUTROPHILS	72.8	%			50.0 - 70.0
							LYMPHOCYTES	15.3	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	10.7	%			2.0 - 14.0
							EOSINOPHILS	0.6	%			< 4.0
							BASOPHILS	0.6	%			< 1.0
							INR-VALUE	1.21				0.83 - 1.43
							aPTT	35.4	sec			26.0 - 40.0
							QUICK (VENOUS)	75	%			> 70
							ERYTHROCYTES	4.6	/pL			3.9 - 5.2
			V1 (WEEK 0)	1	11JAN2010	9:45	HEMOGLOBIN	9.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.43	L/L			0.35 - 0.45
							MCH (HbE)	2.03	fmol	HIGH	NCS	1.59 - 1.99
							MCHC	21.4	mmol/L			19.8 - 22.3
							MCV	94.7	fL			79.4 - 94.8
							THROMBOCYTES	310	/nL			182 - 369
							LEUKOCYTES	6.9	/nL			4.0 - 10.0
							NEUTROPHILS	76.8	%			34.0 - 71.0
							LYMPHOCYTES	11.1	%	LOW	NCS	19.0 - 52.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	046	11	V1 (WEEK 0)	1	11JAN2010	9:45	MONOCYTES	10.5	%		5.0 - 13.0
			V3 (WEEK 12)	87	07APR2010	9:30	EOSINOPHILS	1.5	%		1.0 - 6.0
							BASOPHILS	0.1	%		< 1.0
							ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	93.4	fL		79.4 - 94.8
							THROMBOCYTES	219	/nL		182 - 369
							LEUKOCYTES	6	/nL		4.0 - 10.0
							NEUTROPHILS	75.8	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	13.9	%	LOW NCS	19.0 - 52.0
							MONOCYTES	8.7	%		5.0 - 13.0
							EOSINOPHILS	1.3	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V4 (WEEK 24)	178	07JUL2010	9:30	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	18.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	98.1	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	196	/nL		182 - 369

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	046	11	V4 (WEEK 24)	178	07JUL2010	9:30	LEUKOCYTES	5	/nL		4.0 - 10.0
							NEUTROPHILS	75	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	13.8	%	LOW NCS	19.0 - 52.0
							MONOCYTES	9.4	%		5.0 - 13.0
							EOSINOPHILS	1.6	%		1.0 - 6.0
			V5 (WEEK 36)	255	22SEP2010	11:40	BASOPHILS	0.2	%		< 1.0
							ERYTHROCYTES	5.4	/pL	HIGH NCS	3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.76	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	88.1	fL		79.4 - 94.8
							THROMBOCYTES	247	/nL		182 - 369
							LEUKOCYTES	6.6	/nL		4.0 - 10.0
							NEUTROPHILS	78.4	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	11.4	%	LOW NCS	19.0 - 52.0
							MONOCYTES	9.1	%		5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V6 (WEEK 52)	367	12JAN2011	8:00	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.76	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	046	11	V6 (WEEK 52)	367	12JAN2011	8:00	MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	88.8	fL		79.4 - 94.8
							THROMBOCYTES	265	/nL		182 - 369
							LEUKOCYTES	4.8	/nL		4.0 - 10.0
							NEUTROPHILS	75.3	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	10.1	%	LOW NCS	19.0 - 52.0
							MONOCYTES	11.9	%		5.0 - 13.0
							EOSINOPHILS	2.5	%		1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
			V7 (WEEK 56)	393	07FEB2011	8:15	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.73	fmol		1.59 - 2.00
							MCHC	19.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	88.2	fL		79.4 - 94.8
							THROMBOCYTES	259	/nL		182 - 369
							LEUKOCYTES	5.6	/nL		4.0 - 10.0
							NEUTROPHILS	77	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	12.4	%	LOW NCS	19.0 - 52.0
							MONOCYTES	8.8	%		5.0 - 13.0
							EOSINOPHILS	1.3	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	048	11	SCREENING	-5	17NOV2010	11:10	ERYTHROCYTES	5.3	/pL		4.6 - 6.1
							HEMOGLOBIN	10	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.48	L/L		0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	91.8	fL		79.0 - 92.2
							THROMBOCYTES	178	/nL		163 - 337
							LEUKOCYTES	5.9	/nL		4.2 - 9.1
							NEUTROPHILS	69.3	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	23.1	%		22.0 - 53.0
							MONOCYTES	6.1	%		5.0 - 12.0
							EOSINOPHILS	1.2	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
							INR-VALUE	1.11			0.83 - 1.43
							aPTT	38.4	sec		26.0 - 40.0
							QUICK (VENOUS)	85	%		> 70
			V1 (WEEK 0)	1	22NOV2010	10:30	ERYTHROCYTES	5.5	/pL		4.6 - 6.1
							HEMOGLOBIN	10.7	mmol/L	NCS	8.5 - 10.9
							HEMATOCRIT	0.51	L/L	HIGH NCS	0.40 - 0.50
							MCH (HbE)	1.94	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	92.3	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	191	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	048	11	V1 (WEEK 0)	1	22NOV2010	10:30	LEUKOCYTES	5.2	/nL		4.2 - 9.1
							NEUTROPHILS	64.6	%		34.0 - 68.0
							LYMPHOCYTES	24.3	%		22.0 - 53.0
							MONOCYTES	9.4	%		5.0 - 12.0
							EOSINOPHILS	1.5	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V3 (WEEK 12)	86	15FEB2011	11:00	ERYTHROCYTES	5.2	/pL		4.6 - 6.1
							HEMOGLOBIN	10.3	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.49	L/L		0.40 - 0.50
							MCH (HbE)	1.97	fmol		1.59 - 2.00
							MCHC	20.9	mmol/L		19.8 - 22.3
							MCV	94.4	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	185	/nL		163 - 337
							LEUKOCYTES	5.7	/nL		4.2 - 9.1
							NEUTROPHILS	69	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	23.4	%		22.0 - 53.0
							MONOCYTES	6.3	%		5.0 - 12.0
							EOSINOPHILS	1.1	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V4 (WEEK 24)	176	16MAY2011	10:30	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	10.2	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.49	L/L		0.40 - 0.50
							MCH (HbE)	1.98	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High signi- /Low	ficant	
ACI-91	048	11	V4 (WEEK 24)	176	16MAY2011	10:30	MCHC	20.6	mmol/L			19.8 - 22.3
							MCV	96.1	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	166	/nL			163 - 337
							LEUKOCYTES	5.2	/nL			4.2 - 9.1
							NEUTROPHILS	63.6	%			34.0 - 68.0
							LYMPHOCYTES	26.4	%			22.0 - 53.0
							MONOCYTES	9	%			5.0 - 12.0
			V5 (WEEK 36)	247	26JUL2011	10:40	EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.2	%			< 1.0
							ERYTHROCYTES	5.2	/pL			4.6 - 6.1
							HEMOGLOBIN	10.1	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.57	L/L	HIGH	NCS	0.40 - 0.50
							MCH (HbE)	1.93	fmol			1.59 - 2.00
							MCHC	17.6	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	109.8	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	141	/nL	LOW	NCS	163 - 337
							LEUKOCYTES	5.8	/nL			4.2 - 9.1
							NEUTROPHILS	64.2	%			34.0 - 68.0
							LYMPHOCYTES	24.5	%			22.0 - 53.0
							MONOCYTES	8.7	%			5.0 - 12.0
							EOSINOPHILS	2.4	%			1.0 - 7.0
							BASOPHILS	0.2	%			< 1.0
			V6 (WEEK 52)	360	16NOV2011	10:00	ERYTHROCYTES	5.3	/pL			4.6 - 6.1

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	048	11	V6 (WEEK 52)	360	16NOV2011	10:00	HEMOGLOBIN	10.2	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.49	L/L		0.40 - 0.50
							MCH (HbE)	1.94	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	93.4	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	179	/nL		163 - 337
							LEUKOCYTES	6.1	/nL		4.2 - 9.1
							NEUTROPHILS	70.1	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	21.3	%		22.0 - 53.0
							MONOCYTES	7.1	%	LOW NCS	5.0 - 12.0
							EOSINOPHILS	1.3	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
							ERYTHROCYTES	5.2	/pL		4.6 - 6.1
			V7 (WEEK 56)	395	21DEC2011	11:20	HEMOGLOBIN	10	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.48	L/L		0.40 - 0.50
							MCH (HbE)	1.91	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	92	fL		79.0 - 92.2
							THROMBOCYTES	181	/nL		163 - 337
							LEUKOCYTES	5.3	/nL		4.2 - 9.1
							NEUTROPHILS	62	%		34.0 - 68.0
							LYMPHOCYTES	27.6	%		22.0 - 53.0
							MONOCYTES	8.1	%		5.0 - 12.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	048	11	V7 (WEEK 56)	395	21DEC2011	11:20	EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
	050	21	SCREENING	-51	06SEP2010	14:30	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	20.4	mmol/L		19.8 - 22.3
							MCV	89.4	fL		79.4 - 94.8
							THROMBOCYTES	255	/nL		182 - 369
							LEUKOCYTES	5.8	/nL		4.0 - 10.0
							NEUTROPHILS	56.5	%		34.0 - 71.0
							LYMPHOCYTES	35.8	%		19.0 - 52.0
							MONOCYTES	7.2	%		5.0 - 13.0
							EOSINOPHILS	0.3	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
							INR-VALUE	0.95			0.83 - 1.43
							aPTT	34.9	sec		26.0 - 40.0
							QUICK (VENOUS)	108	%		> 70
			V1 (WEEK 0)	1	27OCT2010	11:45	ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	7.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.8	fmol		1.59 - 2.00

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	050	21	V1 (WEEK 0)	1	27OCT2010	11:45	MCHC	19.8	mmol/L			19.8 - 22.3
							MCV	91.1	fL			79.4 - 94.8
							THROMBOCYTES	230	/nL			182 - 369
							LEUKOCYTES	6.8	/nL			4.0 - 10.0
							NEUTROPHILS	55.2	%			34.0 - 71.0
							LYMPHOCYTES	35.4	%			19.0 - 52.0
							MONOCYTES	8.5	%			5.0 - 13.0
							EOSINOPHILS	0.6	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
			V3 (WEEK 12)	83	17JAN2011	11:15	ERYTHROCYTES	4.6	/pL			3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.43	L/L			0.35 - 0.45
							MCH (HbE)	1.79	fmol			1.59 - 2.00
							MCHC	19.3	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	93	fL			79.4 - 94.8
							THROMBOCYTES	261	/nL			182 - 369
							LEUKOCYTES	8	/nL			4.0 - 10.0
							NEUTROPHILS	61.5	%			34.0 - 71.0
			V4 (WEEK 24)	167	11APR2011	11:20	LYMPHOCYTES	30.3	%			19.0 - 52.0
							MONOCYTES	7.6	%			5.0 - 13.0
							EOSINOPHILS	0.4	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
							ERYTHROCYTES	4.5	/pL			3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	050	21	V4 (WEEK 24)	167	11APR2011	11:20	HEMOGLOBIN	7.9	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.42	L/L			0.35 - 0.45
							MCH (HbE)	1.79	fmol			1.59 - 2.00
							MCHC	18.8	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	95.1	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	228	/nL			182 - 369
							LEUKOCYTES	6.8	/nL			4.0 - 10.0
							NEUTROPHILS	57.3	%			34.0 - 71.0
							LYMPHOCYTES	33.5	%			19.0 - 52.0
							MONOCYTES	8.2	%			5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
			V5 (WEEK 36)	251	04JUL2011	11:50	ERYTHROCYTES	4.4	/pL			3.9 - 5.2
							HEMOGLOBIN	7.9	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.42	L/L			0.35 - 0.45
							MCH (HbE)	1.8	fmol			1.59 - 2.00
							MCHC	18.8	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	95.5	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	270	/nL			182 - 369
							LEUKOCYTES	6.2	/nL			4.0 - 10.0
							NEUTROPHILS	54.5	%			34.0 - 71.0
							LYMPHOCYTES	34.5	%			19.0 - 52.0
							MONOCYTES	9.5	%			5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	050	21	V5 (WEEK 36)	251	04JUL2011	11:50	EOSINOPHILS	1	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V6 (WEEK 52)	363	24OCT2011	9:00	ERYTHROCYTES	4.5	/pL		3.9 - 5.2
							HEMOGLOBIN	8.3	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.83	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	94.1	fL		79.4 - 94.8
							THROMBOCYTES	215	/nL		182 - 369
							LEUKOCYTES	6	/nL		4.0 - 10.0
							NEUTROPHILS	61.4	%		34.0 - 71.0
							LYMPHOCYTES	29.4	%		19.0 - 52.0
							MONOCYTES	8.2	%		5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V7 (WEEK 56)	391	21NOV2011	8:51	ERYTHROCYTES	4.3	/pL		3.9 - 5.2
							HEMOGLOBIN	7.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	19.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	92.8	fL		79.4 - 94.8
							THROMBOCYTES	251	/nL		182 - 369
							LEUKOCYTES	5.6	/nL		4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	050	21	V7 (WEEK 56)	391	21NOV2011	8:51	NEUTROPHILS	48.5	%		34.0 - 71.0
							LYMPHOCYTES	40.4	%		19.0 - 52.0
							MONOCYTES	9.3	%		5.0 - 13.0
							EOSINOPHILS	1.3	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
	052	21	SCREENING	-52	06SEP2010	14:15	ERYTHROCYTES	4.2	/pL		3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	94.2	fL		79.4 - 94.8
							THROMBOCYTES	293	/nL		182 - 369
							LEUKOCYTES	7.2	/nL		4.0 - 10.0
							NEUTROPHILS	55.1	%		34.0 - 71.0
							LYMPHOCYTES	34.2	%		19.0 - 52.0
							MONOCYTES	7.9	%		5.0 - 13.0
							EOSINOPHILS	2.2	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
							INR-VALUE	1.13			0.83 - 1.43
							aPTT	43.6	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	83	%		> 70
		V1 (WEEK 0)		1	28OCT2010	8:15	ERYTHROCYTES	4.1	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	052	21	V1 (WEEK 0)	1	28OCT2010	8:15	HEMOGLOBIN	7.6	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.4	L/L			0.35 - 0.45
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	19.3	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	95.9	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	385	/nL	HIGH	NCS	182 - 369
							LEUKOCYTES	6.2	/nL			4.0 - 10.0
							NEUTROPHILS	57.5	%			34.0 - 71.0
							LYMPHOCYTES	29.4	%			19.0 - 52.0
							MONOCYTES	9.5	%			5.0 - 13.0
							EOSINOPHILS	2.8	%			1.0 - 6.0
							BASOPHILS	0.8	%			< 1.0
			V3 (WEEK 12)	82	17JAN2011	10:45	ERYTHROCYTES	4.8	/pL			3.9 - 5.2
							HEMOGLOBIN	7.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.39	L/L			0.35 - 0.45
							MCH (HbE)	1.56	fmol	LOW	NCS	1.59 - 2.00
							MCHC	19.1	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	81.4	fL			79.4 - 94.8
							THROMBOCYTES	430	/nL	HIGH	NCS	182 - 369
							LEUKOCYTES	6.8	/nL			4.0 - 10.0
							NEUTROPHILS	52.7	%			34.0 - 71.0
							LYMPHOCYTES	36.5	%			19.0 - 52.0
							MONOCYTES	8.6	%			5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant	range
ACI-91	052	21	V3 (WEEK 12)	82	17JAN2011	10:45	EOSINOPHILS	1.8	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
			V4 (WEEK 24)	166	11APR2011	10:45	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	7.3	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.5	fmol	LOW NCS	1.59 - 2.00
							MCHC	18.4	mmol/L	LOW NCS	19.8 - 22.3
							MCV	81.5	fL		79.4 - 94.8
							THROMBOCYTES	413	/nL	HIGH NCS	182 - 369
							LEUKOCYTES	6.9	/nL		4.0 - 10.0
							NEUTROPHILS	50.4	%		34.0 - 71.0
							LYMPHOCYTES	38.6	%		19.0 - 52.0
							MONOCYTES	8.4	%		5.0 - 13.0
							EOSINOPHILS	2	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
			V5 (WEEK 36)	250	04JUL2011	9:24	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	7.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.46	fmol	LOW NCS	1.59 - 2.00
							MCHC	17.7	mmol/L	LOW NCS	19.8 - 22.3
							MCV	82.4	fL		79.4 - 94.8
							THROMBOCYTES	349	/nL		182 - 369
							LEUKOCYTES	6.5	/nL		4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	052	21	V5 (WEEK 36)	250	04JUL2011	9:24	NEUTROPHILS	52	%			34.0 - 71.0
							LYMPHOCYTES	34.6	%			19.0 - 52.0
							MONOCYTES	9.7	%			5.0 - 13.0
							EOSINOPHILS	3.1	%			1.0 - 6.0
							BASOPHILS	0.6	%			< 1.0
			V6 (WEEK 52)	362	24OCT2011	12:15	ERYTHROCYTES	4.8	/pL			3.9 - 5.2
							HEMOGLOBIN	7.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.38	L/L			0.35 - 0.45
							MCH (HbE)	1.5	fmol	LOW	NCS	1.59 - 2.00
							MCHC	19	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	79	fL	LOW	NCS	79.4 - 94.8
							THROMBOCYTES	400	/nL	HIGH	NCS	182 - 369
							LEUKOCYTES	7.3	/nL			4.0 - 10.0
							NEUTROPHILS	57	%			34.0 - 71.0
							LYMPHOCYTES	34.1	%			19.0 - 52.0
							MONOCYTES	6.6	%			5.0 - 13.0
							EOSINOPHILS	1.9	%			1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0
			V7 (WEEK 56)	390	21NOV2011	9:46	ERYTHROCYTES	4.7	/pL			3.9 - 5.2
							HEMOGLOBIN	6.9	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.36	L/L			0.35 - 0.45
							MCH (HbE)	1.48	fmol	LOW	NCS	1.59 - 2.00
							MCHC	19	mmol/L	LOW	NCS	19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		
					Date	Time				High /Low	signi- ficant	Reference range
ACI-91	052	21	V7 (WEEK 56)	390	21NOV2011	9:46	MCV	77.9	fL	LOW	NCS	79.4 - 94.8
							THROMBOCYTES	395	/nL	HIGH	NCS	182 - 369
							LEUKOCYTES	7.3	/nL			4.0 - 10.0
							NEUTROPHILS	62.8	%			34.0 - 71.0
							LYMPHOCYTES	26.4	%			19.0 - 52.0
							MONOCYTES	9	%			5.0 - 13.0
							EOSINOPHILS	1.5	%			1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
	055	5	SCREENING	-21	08MAR2010	11:30	ERYTHROCYTES	5.1	/pL			3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.75	fmol			1.59 - 2.00
							MCHC	20.3	mmol/L			19.8 - 22.3
							MCV	86.5	fL			79.4 - 94.8
							THROMBOCYTES	254	/nL			182 - 369
							LEUKOCYTES	8.2	/nL			4.0 - 10.0
							NEUTROPHILS	52.6	%			34.0 - 71.0
							LYMPHOCYTES	34.8	%			19.0 - 52.0
							MONOCYTES	8.2	%			5.0 - 13.0
							EOSINOPHILS	3.9	%			1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0
							INR-VALUE	1.98		HIGH	NCS	0.83 - 1.43

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	055	5	SCREENING	-21	08MAR2010	11:30	aPTT	104.9	sec	HIGH	NCS	26.0 - 40.0
							QUICK (VENOUS)	41	%	LOW	NCS	> 70
			V1 (WEEK 0)	1	29MAR2010	9:30	ERYTHROCYTES	4.9	/pL			3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.43	L/L			0.35 - 0.45
							MCH (HbE)	1.76	fmol			1.59 - 2.00
							MCHC	20	mmol/L			19.8 - 22.3
							MCV	88	fL			79.4 - 94.8
							THROMBOCYTES	273	/nL			182 - 369
							LEUKOCYTES	6.8	/nL			4.0 - 10.0
							NEUTROPHILS	44.2	%			34.0 - 71.0
							LYMPHOCYTES	38	%			19.0 - 52.0
							MONOCYTES	10.1	%			5.0 - 13.0
							EOSINOPHILS	7	%	HIGH	NCS	1.0 - 6.0
							BASOPHILS	0.7	%			< 1.0
			V6 (WEEK 52)	30	27APR2010	9:15	ERYTHROCYTES	4.6	/pL			3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.49	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.8	fmol			1.59 - 2.00
							MCHC	17.1	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	105.4	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	194	/nL			182 - 369
							LEUKOCYTES	6.4	/nL			4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	055	5	V6 (WEEK 52)	30	27APR2010	9:15	NEUTROPHILS	42.8	%		34.0 - 71.0
							LYMPHOCYTES	41.4	%		19.0 - 52.0
							MONOCYTES	9	%		5.0 - 13.0
							EOSINOPHILS	6.2	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
	057	1	SCREENING	-21	29JUL2010	10:50	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	95.3	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	289	/nL		182 - 369
							LEUKOCYTES	8.1	/nL		4.0 - 10.0
							NEUTROPHILS	81.3	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	11.1	%	LOW NCS	19.0 - 52.0
							MONOCYTES	6.5	%		5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	0.99			0.83 - 1.43
							aPTT	36	sec		26.0 - 40.0
							QUICK (VENOUS)	102	%		> 70
		V1 (WEEK 0)		1	19AUG2010	11:10	ERYTHROCYTES	5.2	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	057	1	V1 (WEEK 0)	1	19AUG2010	11:10	HEMOGLOBIN	9.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.49	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.81	fmol			1.59 - 2.00
							MCHC	19.4	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	93.3	fL			79.4 - 94.8
							THROMBOCYTES	308	/nL			182 - 369
							LEUKOCYTES	7.2	/nL			4.0 - 10.0
							NEUTROPHILS	76.4	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	12.5	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	10	%			5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
			V3 (WEEK 12)	82	08NOV2010	9:45	ERYTHROCYTES	5	/pL			3.9 - 5.2
							HEMOGLOBIN	9.3	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	20	mmol/L			19.8 - 22.3
							MCV	92.2	fL			79.4 - 94.8
							THROMBOCYTES	271	/nL			182 - 369
							LEUKOCYTES	6	/nL			4.0 - 10.0
							NEUTROPHILS	73	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	17.1	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	7.9	%			5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant range	
ACI-91	057	1	V3 (WEEK 12)	82	08NOV2010	9:45	EOSINOPHILS	1.5	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
		V4 (WEEK 24)		170	04FEB2011	9:35	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.51	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.91	fmol		1.59 - 2.00
							MCHC	19	mmol/L	LOW NCS	19.8 - 22.3
							MCV	100.6	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	275	/nL		182 - 369
							LEUKOCYTES	6.1	/nL		4.0 - 10.0
							NEUTROPHILS	76	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	15.5	%	LOW NCS	19.0 - 52.0
							MONOCYTES	6.9	%		5.0 - 13.0
							EOSINOPHILS	1.3	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
	066	16	SCREENING	-31	09AUG2010	10:40	ERYTHROCYTES	4.2	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.1	mmol/L	LOW NCS	8.5 - 10.9
							HEMATOCRIT	0.41	L/L		0.40 - 0.50
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	97.6	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	173	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	066	16	SCREENING	-31	09AUG2010	10:40	LEUKOCYTES	5.9	/nL		4.2 - 9.1
							NEUTROPHILS	44.9	%		34.0 - 68.0
							LYMPHOCYTES	36.5	%		22.0 - 53.0
							MONOCYTES	12.6	%	HIGH NCS	5.0 - 12.0
							EOSINOPHILS	5.1	%		1.0 - 7.0
							BASOPHILS	0.9	%		< 1.0
							INR-VALUE	1.2			0.83 - 1.43
							aPTT	42.2	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	76	%		> 70
			V1 (WEEK 0)	1	09SEP2010	9:25	ERYTHROCYTES	4.2	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.2	mmol/L	LOW NCS	8.5 - 10.9
							HEMATOCRIT	0.4	L/L		0.40 - 0.50
							MCH (HbE)	1.98	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	96.4	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	186	/nL		163 - 337
							LEUKOCYTES	5.8	/nL		4.2 - 9.1
							NEUTROPHILS	51.2	%		34.0 - 68.0
							LYMPHOCYTES	31.4	%		22.0 - 53.0
							MONOCYTES	12.7	%	HIGH NCS	5.0 - 12.0
							EOSINOPHILS	4	%		1.0 - 7.0
							BASOPHILS	0.7	%		< 1.0
			V3 (WEEK 12)	83	30NOV2010	9:15	ERYTHROCYTES	4.3	/pL	LOW NCS	4.6 - 6.1

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	066	16	V3 (WEEK 12)	83	30NOV2010	9:15	HEMOGLOBIN	8.3	mmol/L	LOW	NCS	8.5 - 10.9
							HEMATOCRIT	0.44	L/L			0.40 - 0.50
							MCH (HbE)	1.94	fmol			1.59 - 2.00
							MCHC	19	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	102.1	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	156	/nL	LOW	NCS	163 - 337
							LEUKOCYTES	4.9	/nL			4.2 - 9.1
							NEUTROPHILS	51	%			34.0 - 68.0
							LYMPHOCYTES	28	%			22.0 - 53.0
							MONOCYTES	13.2	%	HIGH	NCS	5.0 - 12.0
							EOSINOPHILS	6.8	%			1.0 - 7.0
							BASOPHILS	1	%	HIGH	NCS	< 1.0
	067	16	SCREENING	-16	02NOV2010	10:40	ERYTHROCYTES	4.3	/pL			3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.4	L/L			0.35 - 0.45
							MCH (HbE)	1.87	fmol			1.59 - 2.00
							MCHC	20.3	mmol/L			19.8 - 22.3
							MCV	91.9	fL			79.4 - 94.8
							THROMBOCYTES	264	/nL			182 - 369
							LEUKOCYTES	4.7	/nL			4.0 - 10.0
							NEUTROPHILS	57.9	%			34.0 - 71.0
							LYMPHOCYTES	29.5	%			19.0 - 52.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	067	16	SCREENING	-16	02NOV2010	10:40	MONOCYTES	9.6	%		5.0 - 13.0
							EOSINOPHILS	2.1	%		1.0 - 6.0
							BASOPHILS	0.9	%		< 1.0
							INR-VALUE	1.5		HIGH NCS	0.83 - 1.43
							aPTT	60.8	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	57	%	LOW NCS	> 70
			V1 (WEEK 0)	1	18NOV2010	8:30	ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.86	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	90.1	fL		79.4 - 94.8
							THROMBOCYTES	262	/nL		182 - 369
							LEUKOCYTES	4.1	/nL		4.0 - 10.0
							NEUTROPHILS	49.6	%		34.0 - 71.0
							LYMPHOCYTES	34.1	%		19.0 - 52.0
							MONOCYTES	12.1	%		5.0 - 13.0
							EOSINOPHILS	3	%		1.0 - 6.0
							BASOPHILS	1.2	%	HIGH NCS	< 1.0
			V6 (WEEK 52)	69	25JAN2011	10:50	ERYTHROCYTES	4.5	/pL		3.9 - 5.2
							HEMOGLOBIN	8.3	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.87	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	067	16	V6 (WEEK 52)	69	25JAN2011	10:50	MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	89.9	fL		79.4 - 94.8
							THROMBOCYTES	249	/nL		182 - 369
							LEUKOCYTES	5.2	/nL		4.0 - 10.0
							NEUTROPHILS	54.8	%		34.0 - 71.0
							LYMPHOCYTES	30.1	%		19.0 - 52.0
							MONOCYTES	10.9	%		5.0 - 13.0
							EOSINOPHILS	2.9	%		1.0 - 6.0
							BASOPHILS	1.3	%	HIGH NCS	< 1.0
			V7 (WEEK 56)	111	08MAR2011	9:05	ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.86	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	92.1	fL		79.4 - 94.8
							THROMBOCYTES	281	/nL		182 - 369
							LEUKOCYTES	5.1	/nL		4.0 - 10.0
							NEUTROPHILS	57.4	%		34.0 - 71.0
							LYMPHOCYTES	29.7	%		19.0 - 52.0
							MONOCYTES	9.3	%		5.0 - 13.0
							EOSINOPHILS	2.6	%		1.0 - 6.0
							BASOPHILS	1	%	HIGH NCS	< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High /Low	signi- ficant	Reference range
					Date	Time						
ACI-91	071	18	SCREENING	-20	20OCT2010	10:05	ERYTHROCYTES	5	/pL	NCS		3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L	NCS		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.88	fmol	NCS		1.59 - 2.00
							MCHC	20.3	mmol/L	NCS		19.8 - 22.3
							MCV	92.4	fL	NCS		79.4 - 94.8
							THROMBOCYTES	351	/nL	NCS		182 - 369
							LEUKOCYTES	7.8	/nL	NCS		4.0 - 10.0
							NEUTROPHILS	82	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	12.6	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	5	%	NCS		5.0 - 13.0
							EOSINOPHILS	0.1	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%	NCS		< 1.0
							INR-VALUE	1.07		NCS		0.83 - 1.43
							aPTT	44.1	sec	HIGH	NCS	26.0 - 40.0
							QUICK (VENOUS)	89	%	NCS		> 70
			V1 (WEEK 0)	1	09NOV2010	11:00	ERYTHROCYTES	5.2	/pL	NCS		3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L	NCS		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.82	fmol	NCS		1.59 - 2.00
							MCHC	20.1	mmol/L	NCS		19.8 - 22.3
							MCV	90.5	fL	NCS		79.4 - 94.8
							THROMBOCYTES	382	/nL	HIGH	NCS	182 - 369

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	071	18	V1 (WEEK 0)	1	09NOV2010	11:00	LEUKOCYTES	6.6	/nL	NCS		4.0 - 10.0
							NEUTROPHILS	56.2	%	NCS		34.0 - 71.0
							LYMPHOCYTES	34.3	%	NCS		19.0 - 52.0
							MONOCYTES	7	%	NCS		5.0 - 13.0
							EOSINOPHILS	2	%	NCS		1.0 - 6.0
							BASOPHILS	0.5	%	NCS		< 1.0
			V3 (WEEK 12)	87	03FEB2011	10:07	ERYTHROCYTES	5	/pL	NCS		3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L	NCS		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS		0.35 - 0.45
							MCH (HbE)	1.84	fmol	NCS		1.59 - 2.00
							MCHC	20	mmol/L	NCS		19.8 - 22.3
							MCV	92.2	fL	NCS		79.4 - 94.8
							THROMBOCYTES	412	/nL	HIGH NCS		182 - 369
							LEUKOCYTES	7.7	/nL	NCS		4.0 - 10.0
							NEUTROPHILS	71.5	%	HIGH NCS		34.0 - 71.0
							LYMPHOCYTES	22	%	NCS		19.0 - 52.0
							MONOCYTES	6.1	%	NCS		5.0 - 13.0
							EOSINOPHILS	0.1	%	LOW NCS		1.0 - 6.0
							BASOPHILS	0.3	%	NCS		< 1.0
			V4 (WEEK 24)	177	04MAY2011	9:35	ERYTHROCYTES	5.2	/pL	NCS		3.9 - 5.2
							HEMOGLOBIN	9.7	mmol/L	NCS		6.9 - 9.7
							HEMATOCRIT	0.49	L/L	HIGH NCS		0.35 - 0.45
							MCH (HbE)	1.85	fmol	NCS		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	071	18	V4 (WEEK 24)	177	04MAY2011	9:35	MCHC	19.8	mmol/L	NCS	19.8 - 22.3
							MCV	93.7	fL	NCS	79.4 - 94.8
							THROMBOCYTES	388	/nL	HIGH NCS	182 - 369
							LEUKOCYTES	6.2	/nL	NCS	4.0 - 10.0
							NEUTROPHILS	64.9	%	NCS	34.0 - 71.0
							LYMPHOCYTES	26.3	%	NCS	19.0 - 52.0
							MONOCYTES	6.6	%	NCS	5.0 - 13.0
							EOSINOPHILS	1.6	%	NCS	1.0 - 6.0
							BASOPHILS	0.6	%	NCS	< 1.0
			V5 (WEEK 36)	253	19JUL2011	9:41	ERYTHROCYTES	5	/pL	NCS	3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L	NCS	6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.9	fmol	NCS	1.59 - 2.00
							MCHC	20	mmol/L	NCS	19.8 - 22.3
							MCV	94.8	fL	NCS	79.4 - 94.8
							THROMBOCYTES	366	/nL	NCS	182 - 369
							LEUKOCYTES	8.2	/nL	NCS	4.0 - 10.0
							NEUTROPHILS	77.2	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	17.9	%	LOW NCS	19.0 - 52.0
							MONOCYTES	4.5	%	LOW NCS	5.0 - 13.0
							EOSINOPHILS	0.2	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.2	%	NCS	< 1.0
			V6 (WEEK 52)	374	17NOV2011	11:02	ERYTHROCYTES	4.9	/pL	NCS	3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	071	18	V6 (WEEK 52)	374	17NOV2011	11:02	HEMOGLOBIN	9.2	mmol/L	NCS	6.9 - 9.7
							HEMATOCRIT	0.45	L/L	NCS	0.35 - 0.45
							MCH (HbE)	1.88	fmol	NCS	1.59 - 2.00
							MCHC	20.6	mmol/L	NCS	19.8 - 22.3
							MCV	91.2	fL	NCS	79.4 - 94.8
							THROMBOCYTES	386	/nL	HIGH NCS	182 - 369
							LEUKOCYTES	10	/nL	NCS	4.0 - 10.0
							NEUTROPHILS	72.3	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	21.7	%	NCS	19.0 - 52.0
							MONOCYTES	5.5	%	NCS	5.0 - 13.0
							EOSINOPHILS	0.3	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.2	%	NCS	< 1.0
			V7 (WEEK 56)	392	05DEC2011	12:01	ERYTHROCYTES	5.2	/pL	NCS	3.9 - 5.2
							HEMOGLOBIN	9.6	mmol/L	NCS	6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.85	fmol	NCS	1.59 - 2.00
							MCHC	20.6	mmol/L	NCS	19.8 - 22.3
							MCV	90	fL	NCS	79.4 - 94.8
							THROMBOCYTES	421	/nL	HIGH NCS	182 - 369
							LEUKOCYTES	6.6	/nL	NCS	4.0 - 10.0
							NEUTROPHILS	57.3	%	NCS	34.0 - 71.0
							LYMPHOCYTES	34.5	%	NCS	19.0 - 52.0
							MONOCYTES	6.5	%	NCS	5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	071	18	V7 (WEEK 56)	392	05DEC2011	12:01	EOSINOPHILS	1.1	%	NCS	1.0 - 6.0
							BASOPHILS	0.6	%	NCS	< 1.0
	080	13	SCREENING	-10	08NOV2010	10:27	ERYTHROCYTES	5.4	/pL	HIGH NCS	3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.75	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	88.4	fL		79.4 - 94.8
							THROMBOCYTES	251	/nL		182 - 369
							LEUKOCYTES	8	/nL		4.0 - 10.0
							NEUTROPHILS	74.1	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	18.2	%	LOW NCS	19.0 - 52.0
							MONOCYTES	6.9	%		5.0 - 13.0
							EOSINOPHILS	0.4	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	1.15			0.83 - 1.43
							aPTT	35	sec		26.0 - 40.0
							QUICK (VENOUS)	81	%		> 70
			V1 (WEEK 0)	1	18NOV2010	12:30	ERYTHROCYTES	5.3	/pL	HIGH NCS	3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.72	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	080	13	V1 (WEEK 0)	1	18NOV2010	12:30	MCHC	19.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	87.4	fL			79.4 - 94.8
							THROMBOCYTES	218	/nL			182 - 369
							LEUKOCYTES	5.8	/nL			4.0 - 10.0
							NEUTROPHILS	68.8	%			34.0 - 71.0
							LYMPHOCYTES	21.9	%			19.0 - 52.0
							MONOCYTES	8.3	%			5.0 - 13.0
							EOSINOPHILS	0.5	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0
			V3 (WEEK 12)	84	09FEB2011	11:30	ERYTHROCYTES	5.2	/pL			3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.8	fmol			1.59 - 2.00
							MCHC	19.9	mmol/L			19.8 - 22.3
							MCV	90.8	fL			79.4 - 94.8
							THROMBOCYTES	234	/nL			182 - 369
							LEUKOCYTES	6.2	/nL			4.0 - 10.0
							NEUTROPHILS	72.6	%	HIGH	NCS	34.0 - 71.0
			V6 (WEEK 52)	196	01JUN2011	12:30	LYMPHOCYTES	18.6	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	7.6	%			5.0 - 13.0
							EOSINOPHILS	0.6	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.6	%			< 1.0
							ERYTHROCYTES	5.1	/pL			3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	080	13	V6 (WEEK 52)	196	01JUN2011	12:30	HEMOGLOBIN	9.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.51	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.82	fmol			1.59 - 2.00
							MCHC	18	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	100.6	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	207	/nL			182 - 369
							LEUKOCYTES	5.4	/nL			4.0 - 10.0
							NEUTROPHILS	69.7	%			34.0 - 71.0
							LYMPHOCYTES	22.6	%			19.0 - 52.0
							MONOCYTES	6.9	%			5.0 - 13.0
							EOSINOPHILS	0.6	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
	081	17	SCREENING	-10	04OCT2010	11:20	ERYTHROCYTES	5.1	/pL			4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.46	L/L			0.40 - 0.50
							MCH (HbE)	1.77	fmol			1.59 - 2.00
							MCHC	19.5	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	90.6	fL			79.0 - 92.2
							THROMBOCYTES	263	/nL			163 - 337
							LEUKOCYTES	7.7	/nL			4.2 - 9.1
							NEUTROPHILS	59.6	%			34.0 - 68.0
							LYMPHOCYTES	24.7	%			22.0 - 53.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	081	17	SCREENING	-10	04OCT2010	11:20	MONOCYTES	10.4	%		5.0 - 12.0
							EOSINOPHILS	4.9	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	1.14			0.83 - 1.43
							aPTT	40.6	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	82	%		> 70
			V1 (WEEK 0)	1	14OCT2010	10:00	ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	89.9	fL		79.0 - 92.2
							THROMBOCYTES	262	/nL		163 - 337
							LEUKOCYTES	8	/nL		4.2 - 9.1
							NEUTROPHILS	56.6	%		34.0 - 68.0
							LYMPHOCYTES	28.9	%		22.0 - 53.0
							MONOCYTES	8.4	%		5.0 - 12.0
							EOSINOPHILS	5.7	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V3 (WEEK 12)	89	10JAN2011	11:15	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.77	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	11:15	MCHC	19.5	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	90.5	fL			79.0 - 92.2
							THROMBOCYTES	263	/nL			163 - 337
							LEUKOCYTES	7.7	/nL			4.2 - 9.1
							NEUTROPHILS	61.2	%			34.0 - 68.0
							LYMPHOCYTES	23	%			22.0 - 53.0
							MONOCYTES	10.7	%			5.0 - 12.0
							EOSINOPHILS	4.6	%			1.0 - 7.0
			V4 (WEEK 24)	175	06APR2011	9:30	BASOPHILS	0.5	%			< 1.0
							ERYTHROCYTES	4.2	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	8.6	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.43	L/L			0.40 - 0.50
							MCH (HbE)	2.05	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	20.1	mmol/L			19.8 - 22.3
							MCV	101.9	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	221	/nL			163 - 337
							LEUKOCYTES	4.4	/nL			4.2 - 9.1
							NEUTROPHILS	69.2	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	20.9	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	7.1	%			5.0 - 12.0
							EOSINOPHILS	2.3	%			1.0 - 7.0
			V5 (WEEK 36)	250	20JUN2011	11:00	BASOPHILS	0.5	%			< 1.0
							ERYTHROCYTES	5.1	/pL			4.6 - 6.1

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	081	17	V5 (WEEK 36)	250	20JUN2011	11:00	HEMOGLOBIN	9.1	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.48	L/L			0.40 - 0.50
							MCH (HbE)	1.79	fmol			1.59 - 2.00
							MCHC	19.2	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	93.5	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	242	/nL			163 - 337
							LEUKOCYTES	8.4	/nL			4.2 - 9.1
							NEUTROPHILS	58.4	%			34.0 - 68.0
							LYMPHOCYTES	25.9	%			22.0 - 53.0
							MONOCYTES	10.3	%			5.0 - 12.0
							EOSINOPHILS	4.9	%			1.0 - 7.0
							BASOPHILS	0.5	%			< 1.0
			V6 (WEEK 52)	376	24OCT2011	10:35	ERYTHROCYTES	4.7	/pL			4.6 - 6.1
							HEMOGLOBIN	8.4	mmol/L	LOW	NCS	8.5 - 10.9
							HEMATOCRIT	0.41	L/L			0.40 - 0.50
							MCH (HbE)	1.8	fmol			1.59 - 2.00
							MCHC	20.4	mmol/L			19.8 - 22.3
							MCV	88.3	fL			79.0 - 92.2
							THROMBOCYTES	348	/nL	HIGH	NCS	163 - 337
							LEUKOCYTES	6.3	/nL			4.2 - 9.1
							NEUTROPHILS	61.9	%			34.0 - 68.0
							LYMPHOCYTES	19.1	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	13.1	%	HIGH	NCS	5.0 - 12.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
ACI-91	081	17	V6 (WEEK 52)	376	24OCT2011	10:35	EOSINOPHILS	5.4	%			1.0 - 7.0
							BASOPHILS	0.5	%			< 1.0
			V7 (WEEK 56)	405	22NOV2011	10:45	ERYTHROCYTES	4.5	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	8.1	mmol/L	LOW	NCS	8.5 - 10.9
							HEMATOCRIT	0.4	L/L			0.40 - 0.50
							MCH (HbE)	1.77	fmol			1.59 - 2.00
							MCHC	20.3	mmol/L			19.8 - 22.3
							MCV	87.7	fL			79.0 - 92.2
							THROMBOCYTES	275	/nL			163 - 337
							LEUKOCYTES	8.1	/nL			4.2 - 9.1
							NEUTROPHILS	59.5	%			34.0 - 68.0
							LYMPHOCYTES	24.6	%			22.0 - 53.0
							MONOCYTES	11.7	%			5.0 - 12.0
							EOSINOPHILS	3.7	%			1.0 - 7.0
							BASOPHILS	0.5	%			< 1.0
	083	17	SCREENING	-15	26OCT2010	11:30	ERYTHROCYTES	3.9	/pL			3.9 - 5.2
							HEMOGLOBIN	7.5	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.35	L/L			0.35 - 0.45
							MCH (HbE)	1.92	fmol			1.59 - 2.00
							MCHC	21.6	mmol/L			19.8 - 22.3
							MCV	88.8	fL			79.4 - 94.8
							THROMBOCYTES	204	/nL			182 - 369

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	083	17	SCREENING	-15	26OCT2010	11:30	LEUKOCYTES	7.8	/nL		4.0 - 10.0
							NEUTROPHILS	64.3	%		34.0 - 71.0
							LYMPHOCYTES	19.7	%		19.0 - 52.0
							MONOCYTES	7.9	%		5.0 - 13.0
							EOSINOPHILS	7.7	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE				0.83 - 1.43
							aPTT		sec		26.0 - 40.0
							QUICK (VENOUS)		%		> 70
			V1 (WEEK 0)	1	10NOV2010	9:25	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	89.8	fL		79.4 - 94.8
							THROMBOCYTES	342	/nL		182 - 369
							LEUKOCYTES	6.3	/nL		4.0 - 10.0
							NEUTROPHILS	64.1	%		34.0 - 71.0
							LYMPHOCYTES	24.2	%		19.0 - 52.0
							MONOCYTES	9.5	%		5.0 - 13.0
							EOSINOPHILS	1.6	%		1.0 - 6.0
			V4 (WEEK 24)	168	26APR2011	10:15	BASOPHILS	0.6	%		< 1.0
							ERYTHROCYTES	5.1	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	083	17	V4 (WEEK 24)	168	26APR2011	10:15	HEMOGLOBIN	7.8	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.42	L/L			0.35 - 0.45
							MCH (HbE)	1.53	fmol	LOW	NCS	1.59 - 2.00
							MCHC	18.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	82	fL			79.4 - 94.8
							THROMBOCYTES	263	/nL			182 - 369
							LEUKOCYTES	5.6	/nL			4.0 - 10.0
							NEUTROPHILS	40.5	%			34.0 - 71.0
							LYMPHOCYTES	50.4	%			19.0 - 52.0
							MONOCYTES	5.5	%			5.0 - 13.0
							EOSINOPHILS	2.9	%			1.0 - 6.0
							BASOPHILS	0.7	%			< 1.0
		V5 (WEEK 36)	258	25JUL2011	10:50	ERYTHROCYTES	4.6	/pL			3.9 - 5.2	
						HEMOGLOBIN	8.7	mmol/L			6.9 - 9.7	
						HEMATOCRIT	0.43	L/L			0.35 - 0.45	
						MCH (HbE)	1.88	fmol			1.59 - 2.00	
						MCHC	20.3	mmol/L			19.8 - 22.3	
						MCV	92.7	fL			79.4 - 94.8	
						THROMBOCYTES	230	/nL			182 - 369	
						LEUKOCYTES	5.8	/nL			4.0 - 10.0	
						NEUTROPHILS	58.3	%			34.0 - 71.0	
						LYMPHOCYTES	29.5	%			19.0 - 52.0	
						MONOCYTES	8.7	%			5.0 - 13.0	

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	083	17	V5 (WEEK 36)	258	25JUL2011	10:50	EOSINOPHILS	2.1	%	HIGH NCS	1.0 - 6.0
			BASOPHILS	1.4	%	< 1.0					
			V6 (WEEK 52)	365	09NOV2011	10:20	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
			HEMOGLOBIN	8.9	mmol/L	6.9 - 9.7					
			HEMATOCRIT	0.43	L/L	0.35 - 0.45					
			MCH (HbE)	1.93	fmol	1.59 - 2.00					
			MCHC	20.8	mmol/L	19.8 - 22.3					
			MCV	92.7	fL	79.4 - 94.8					
			THROMBOCYTES	206	/nL	182 - 369					
			LEUKOCYTES	8.6	/nL	4.0 - 10.0					
			NEUTROPHILS	60.3	%	34.0 - 71.0					
			LYMPHOCYTES	29.5	%	19.0 - 52.0					
			MONOCYTES	6.8	%	5.0 - 13.0					
			EOSINOPHILS	3.1	%	1.0 - 6.0					
			BASOPHILS	0.3	%	< 1.0					
			V7 (WEEK 56)	392	06DEC2011	10:20	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
			HEMOGLOBIN	8.9	mmol/L	6.9 - 9.7					
			HEMATOCRIT	0.44	L/L	0.35 - 0.45					
			MCH (HbE)	1.88	fmol	1.59 - 2.00					
			MCHC	20.3	mmol/L	19.8 - 22.3					
			MCV	92.2	fL	79.4 - 94.8					
			THROMBOCYTES	302	/nL	182 - 369					
			LEUKOCYTES	6	/nL	4.0 - 10.0					

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	083	17	V7 (WEEK 56)	392	06DEC2011	10:20	NEUTROPHILS	77.7	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	15.1	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	6.7	%			5.0 - 13.0
							EOSINOPHILS	0.2	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
	087	16	SCREENING	-20	09NOV2010	9:05	ERYTHROCYTES	4.2	/pL			3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.39	L/L			0.35 - 0.45
							MCH (HbE)	1.88	fmol			1.59 - 2.00
							MCHC	20.2	mmol/L			19.8 - 22.3
							MCV	93.3	fL			79.4 - 94.8
							THROMBOCYTES	239	/nL			182 - 369
							LEUKOCYTES	5.7	/nL			4.0 - 10.0
							NEUTROPHILS	39.8	%			34.0 - 71.0
							LYMPHOCYTES	35.8	%			19.0 - 52.0
							MONOCYTES	12.9	%			5.0 - 13.0
							EOSINOPHILS	9.9	%	HIGH	NCS	1.0 - 6.0
							BASOPHILS	1.6	%	HIGH	NCS	< 1.0
							INR-VALUE	1.14				0.83 - 1.43
							aPTT	40.2	sec	HIGH	NCS	26.0 - 40.0
							QUICK (VENOUS)	82	%			> 70
		V1 (WEEK 0)		1	29NOV2010	10:10	ERYTHROCYTES	4	/pL			3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.	Reference range
					Date	Time				High signi- /Low ficant	
ACI-91	087	16	V1 (WEEK 0)	1	29NOV2010	10:10	HEMOGLOBIN	7.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.38	L/L		0.35 - 0.45
							MCH (HbE)	1.91	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	94	fL		79.4 - 94.8
							THROMBOCYTES	217	/nL		182 - 369
							LEUKOCYTES	6.5	/nL		4.0 - 10.0
							NEUTROPHILS	57.3	%		34.0 - 71.0
							LYMPHOCYTES	26	%		19.0 - 52.0
							MONOCYTES	9.4	%		5.0 - 13.0
							EOSINOPHILS	6.8	%	HIGH NCS	1.0 - 6.0
			BASOPHILS	0.5	%	< 1.0					
			V3 (WEEK 12)	81	17FEB2011	9:35	ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.92	fmol		1.59 - 2.00
							MCHC	20.7	mmol/L		19.8 - 22.3
							MCV	92.5	fL		79.4 - 94.8
							THROMBOCYTES	237	/nL		182 - 369
							LEUKOCYTES	5.9	/nL		4.0 - 10.0
							NEUTROPHILS	45.9	%		34.0 - 71.0
							LYMPHOCYTES	29.9	%		19.0 - 52.0
							MONOCYTES	10.5	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	087	16	V3 (WEEK 12)	81	17FEB2011	9:35	EOSINOPHILS	12.5	%	HIGH	NCS	1.0 - 6.0
							BASOPHILS	1.2	%	HIGH	NCS	< 1.0
			V4 (WEEK 24)	169	16MAY2011	11:00	ERYTHROCYTES	4	/pL			3.9 - 5.2
							HEMOGLOBIN	7.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.38	L/L			0.35 - 0.45
							MCH (HbE)	1.87	fmol			1.59 - 2.00
							MCHC	19.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	94.5	fL			79.4 - 94.8
							THROMBOCYTES	277	/nL			182 - 369
							LEUKOCYTES	6.3	/nL			4.0 - 10.0
							NEUTROPHILS	51.1	%			34.0 - 71.0
							LYMPHOCYTES	29.3	%			19.0 - 52.0
							MONOCYTES	8.9	%			5.0 - 13.0
							EOSINOPHILS	9.7	%	HIGH	NCS	1.0 - 6.0
							BASOPHILS	1	%	HIGH	NCS	< 1.0
			V5 (WEEK 36)	255	10AUG2011	10:20	ERYTHROCYTES	4.3	/pL			3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.41	L/L			0.35 - 0.45
							MCH (HbE)	1.88	fmol			1.59 - 2.00
							MCHC	19.8	mmol/L			19.8 - 22.3
							MCV	94.9	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	243	/nL			182 - 369
							LEUKOCYTES	6.7	/nL			4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	087	16	V5 (WEEK 36)	255	10AUG2011	10:20	NEUTROPHILS	39.8	%		34.0 - 71.0
							LYMPHOCYTES	34	%		19.0 - 52.0
							MONOCYTES	7.7	%		5.0 - 13.0
							EOSINOPHILS	16.8	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	1.7	%	HIGH NCS	< 1.0
			V6 (WEEK 52)	365	28NOV2011	10:15	ERYTHROCYTES	4.3	/pL		3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.89	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	93.2	fL		79.4 - 94.8
							THROMBOCYTES	282	/nL		182 - 369
							LEUKOCYTES	5.1	/nL		4.0 - 10.0
							NEUTROPHILS	45.6	%		34.0 - 71.0
							LYMPHOCYTES	31.6	%		19.0 - 52.0
							MONOCYTES	11.7	%		5.0 - 13.0
							EOSINOPHILS	10.3	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	0.8	%		< 1.0
			V7 (WEEK 56)	395	28DEC2011	12:00	ERYTHROCYTES	4.3	/pL		3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	087	16	V7 (WEEK 56)	395	28DEC2011	12:00	MCV	91.6	fL		79.4 - 94.8
							THROMBOCYTES	257	/nL		182 - 369
							LEUKOCYTES	7.4	/nL		4.0 - 10.0
							NEUTROPHILS	56.1	%		34.0 - 71.0
							LYMPHOCYTES	27.8	%		19.0 - 52.0
							MONOCYTES	9.1	%		5.0 - 13.0
							EOSINOPHILS	6.1	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	0.9	%		< 1.0
	089	5	SCREENING	-28	19OCT2010	12:00	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.42	L/L		0.35 - 0.45
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	21.1	mmol/L		19.8 - 22.3
							MCV	88.7	fL		79.4 - 94.8
							THROMBOCYTES	189	/nL		182 - 369
							LEUKOCYTES	8.7	/nL		4.0 - 10.0
							NEUTROPHILS	62.9	%		34.0 - 71.0
							LYMPHOCYTES	27	%		19.0 - 52.0
							MONOCYTES	7.9	%		5.0 - 13.0
							EOSINOPHILS	1.7	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
							INR-VALUE	1.06			0.83 - 1.43

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	089	5	SCREENING	-28	19OCT2010	12:00	aPTT	39.7	sec		26.0 - 40.0
							QUICK (VENOUS)	92	%		> 70
			V1 (WEEK 0)	1	16NOV2010	12:00	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	91	fL		79.4 - 94.8
							THROMBOCYTES	202	/nL		182 - 369
							LEUKOCYTES	7.4	/nL		4.0 - 10.0
							NEUTROPHILS	58.7	%		34.0 - 71.0
							LYMPHOCYTES	30.9	%		19.0 - 52.0
							MONOCYTES	8.1	%		5.0 - 13.0
							EOSINOPHILS	1.9	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
			V3 (WEEK 12)	84	07FEB2011	11:30	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.78	fmol		1.59 - 2.00
							MCHC	19.9	mmol/L		19.8 - 22.3
							MCV	89.3	fL		79.4 - 94.8
							THROMBOCYTES	201	/nL		182 - 369
							LEUKOCYTES	7.5	/nL		4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	089	5	V3 (WEEK 12)	84	07FEB2011	11:30	NEUTROPHILS	63.8	%		34.0 - 71.0
							LYMPHOCYTES	25.2	%		19.0 - 52.0
							MONOCYTES	8.4	%		5.0 - 13.0
							EOSINOPHILS	2.1	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V4 (WEEK 24)	168	02MAY2011	10:15	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.78	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	89.3	fL		79.4 - 94.8
							THROMBOCYTES	201	/nL		182 - 369
							LEUKOCYTES	8.1	/nL		4.0 - 10.0
							NEUTROPHILS	65.9	%		34.0 - 71.0
							LYMPHOCYTES	24.4	%		19.0 - 52.0
							MONOCYTES	8.2	%		5.0 - 13.0
							EOSINOPHILS	1.1	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
			V5 (WEEK 36)	252	25JUL2011	12:00	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	8.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	089	5	V5 (WEEK 36)	252	25JUL2011	12:00	MCV	90.6	fL			79.4 - 94.8
							THROMBOCYTES	189	/nL			182 - 369
							LEUKOCYTES	8.3	/nL			4.0 - 10.0
							NEUTROPHILS	66.6	%			34.0 - 71.0
							LYMPHOCYTES	25.9	%			19.0 - 52.0
							MONOCYTES	6.2	%			5.0 - 13.0
							EOSINOPHILS	1.1	%			1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
			V6 (WEEK 52)	364	14NOV2011	12:30	ERYTHROCYTES	4.7	/pL			3.9 - 5.2
							HEMOGLOBIN	8.5	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.42	L/L			0.35 - 0.45
							MCH (HbE)	1.79	fmol			1.59 - 2.00
							MCHC	20.4	mmol/L			19.8 - 22.3
							MCV	88	fL			79.4 - 94.8
							THROMBOCYTES	168	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	7.3	/nL			4.0 - 10.0
			V7 (WEEK 56)	394	14DEC2011	13:00	NEUTROPHILS	62.1	%			34.0 - 71.0
							LYMPHOCYTES	28.5	%			19.0 - 52.0
							MONOCYTES	7.9	%			5.0 - 13.0
							EOSINOPHILS	1.4	%			1.0 - 6.0
							BASOPHILS	0.1	%			< 1.0
							ERYTHROCYTES	4.9	/pL		NCS	3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L		NCS	6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	089	5	V7 (WEEK 56)	394	14DEC2011	13:00	HEMATOCRIT	0.43	L/L	NCS	0.35 - 0.45
							MCH (HbE)	1.81	fmol	NCS	1.59 - 2.00
							MCHC	20.6	mmol/L	NCS	19.8 - 22.3
							MCV	87.8	fL	NCS	79.4 - 94.8
							THROMBOCYTES	196	/nL	NCS	182 - 369
							LEUKOCYTES	9.5	/nL	NCS	4.0 - 10.0
							NEUTROPHILS	66.7	%	NCS	34.0 - 71.0
							LYMPHOCYTES	24.1	%	NCS	19.0 - 52.0
							MONOCYTES	7.6	%	NCS	5.0 - 13.0
							EOSINOPHILS	1.2	%	NCS	1.0 - 6.0
							BASOPHILS	0.4	%	NCS	< 1.0
	093	17	SCREENING	-3	29NOV2010	12:30	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	2	fmol		1.59 - 2.00
							MCHC	21.1	mmol/L		19.8 - 22.3
							MCV	94.6	fL		79.4 - 94.8
							THROMBOCYTES	219	/nL		182 - 369
							LEUKOCYTES	6.4	/nL		4.0 - 10.0
							NEUTROPHILS	66.2	%		34.0 - 71.0
							LYMPHOCYTES	26.4	%		19.0 - 52.0
							MONOCYTES	6.6	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	093	17	SCREENING	-3	29NOV2010	12:30	EOSINOPHILS	0.5	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
							INR-VALUE	1.15				0.83 - 1.43
							aPTT	35.8	sec			26.0 - 40.0
							QUICK (VENOUS)	81	%			> 70
			V1 (WEEK 0)	1	02DEC2010	8:30	ERYTHROCYTES	4.9	/pL	HIGH	NCS	3.9 - 5.2
							HEMOGLOBIN	9.8	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.47	L/L			0.35 - 0.45
							MCH (HbE)	2	fmol			1.59 - 2.00
							MCHC	20.9	mmol/L			19.8 - 22.3
							MCV	95.9	fL			79.4 - 94.8
							THROMBOCYTES	196	/nL			182 - 369
							LEUKOCYTES	10.4	/nL			4.0 - 10.0
							NEUTROPHILS	79.6	%			34.0 - 71.0
							LYMPHOCYTES	13.9	%			19.0 - 52.0
							MONOCYTES	5.6	%			5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
							ERYTHROCYTES	4.9	/pL			3.9 - 5.2
			V3 (WEEK 12)	86	25FEB2011	11:35	HEMOGLOBIN	9.9	mmol/L	HIGH	NCS	6.9 - 9.7
							HEMATOCRIT	0.48	L/L			0.35 - 0.45
							MCH (HbE)	2.03	fmol			1.59 - 2.00
							MCHC	20.6	mmol/L			19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	093	17	V3 (WEEK 12)	86	25FEB2011	11:35	MCV	98.2	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	230	/nL			182 - 369
							LEUKOCYTES	6.3	/nL			4.0 - 10.0
							NEUTROPHILS	66.4	%			34.0 - 71.0
							LYMPHOCYTES	26.1	%			19.0 - 52.0
							MONOCYTES	6.5	%			5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 6.0
			V4 (WEEK 24)	173	23MAY2011	11:45	BASOPHILS	0.2	%			< 1.0
							ERYTHROCYTES	4.9	/pL			3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.45	L/L			0.35 - 0.45
							MCH (HbE)	1.8	fmol			1.59 - 2.00
							MCHC	19.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	91.7	fL			79.4 - 94.8
							THROMBOCYTES	256	/nL			182 - 369
							LEUKOCYTES	8.2	/nL			4.0 - 10.0
							NEUTROPHILS	64.5	%			34.0 - 71.0
							LYMPHOCYTES	21.3	%			19.0 - 52.0
							MONOCYTES	10.1	%			5.0 - 13.0
							EOSINOPHILS	3.7	%			1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0
		17	V5 (WEEK 36)	258	16AUG2011	10:30	ERYTHROCYTES	4.7	/pL			3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L			6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	093	17	V5 (WEEK 36)	258	16AUG2011	10:30	HEMATOCRIT	0.46	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.95	fmol			1.59 - 2.00
							MCHC	20.2	mmol/L	HIGH	NCS	19.8 - 22.3
							MCV	96.8	fL			79.4 - 94.8
							THROMBOCYTES	181	/nL			182 - 369
							LEUKOCYTES	8.2	/nL			4.0 - 10.0
							NEUTROPHILS	48.7	%			34.0 - 71.0
							LYMPHOCYTES	39.6	%			19.0 - 52.0
							MONOCYTES	8.4	%	LOW	NCS	5.0 - 13.0
							EOSINOPHILS	2.8	%			1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0
		V6 (WEEK 52)		370	06DEC2011	10:40	ERYTHROCYTES	4.8	/pL			3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.89	fmol			1.59 - 2.00
							MCHC	20.5	mmol/L			19.8 - 22.3
							MCV	92.3	fL			79.4 - 94.8
							THROMBOCYTES	303	/nL			182 - 369
							LEUKOCYTES	5.8	/nL			4.0 - 10.0
							NEUTROPHILS	77.7	%			34.0 - 71.0
							LYMPHOCYTES	14.3	%			19.0 - 52.0
							MONOCYTES	7.4	%	HIGH	NCS	5.0 - 13.0
							EOSINOPHILS	0.3	%			1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	093	17	V6 (WEEK 52)	370	06DEC2011	10:40	BASOPHILS	0.3	%		< 1.0
			V7 (WEEK 56)	392	28DEC2011	10:15	ERYTHROCYTES	4.3	/pL		3.9 - 5.2
							HEMOGLOBIN	8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	92.4	fL		79.4 - 94.8
							THROMBOCYTES	269	/nL		182 - 369
							LEUKOCYTES	6.1	/nL		4.0 - 10.0
							NEUTROPHILS	56.2	%		34.0 - 71.0
							LYMPHOCYTES	21.4	%		19.0 - 52.0
							MONOCYTES	10	%		5.0 - 13.0
							EOSINOPHILS	10.6	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	1.8	%	HIGH NCS	< 1.0
	097	12	SCREENING	-21	27OCT2010	8:30	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9.8	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.99	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	96.3	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	177	/nL		163 - 337
							LEUKOCYTES	7.2	/nL		4.2 - 9.1

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	097	12	SCREENING	-21	27OCT2010	8:30	NEUTROPHILS	58.9	%		34.0 - 68.0
							LYMPHOCYTES	28.1	%		22.0 - 53.0
							MONOCYTES	9.5	%		5.0 - 12.0
							EOSINOPHILS	3.2	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
							INR-VALUE	1.07			0.83 - 1.43
							aPTT	35.7	sec		26.0 - 40.0
			V1 (WEEK 0)	1	17NOV2010	8:30	QUICK (VENOUS)	89	%		> 70
							ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.91	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	94.6	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	197	/nL		163 - 337
							LEUKOCYTES	6.6	/nL		4.2 - 9.1
							NEUTROPHILS	58.6	%		34.0 - 68.0
							LYMPHOCYTES	29.6	%		22.0 - 53.0
							MONOCYTES	8.9	%		5.0 - 12.0
							EOSINOPHILS	2.6	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
			V3 (WEEK 12)	85	09FEB2011	8:15	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9.7	mmol/L		8.5 - 10.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	097	12	V3 (WEEK 12)	85	09FEB2011	8:15	HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.98	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	95.7	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	182	/nL		163 - 337
							LEUKOCYTES	6.3	/nL		4.2 - 9.1
							NEUTROPHILS	62.4	%		34.0 - 68.0
							LYMPHOCYTES	28.4	%		22.0 - 53.0
							MONOCYTES	7	%		5.0 - 12.0
							EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
Placebo	001	1	SCREENING	-7	02APR2009	10:40	ERYTHROCYTES	5.1	/pL		3.8 - 5.3
							HEMOGLOBIN	9.1	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.47	L/L		0.35 - 0.47
							MCH (HbE)	1.79	fmol		1.74 - 1.99
							MCHC	19.5	mmol/L	LOW NCS	19.9 - 22.9
							MCV	91.6	fL		82.0 - 96.0
							THROMBOCYTES	281	/nL		150 - 400
							LEUKOCYTES	5.6	/nL		4.0 - 9.0
							NEUTROPHILS	71.6	%	HIGH NCS	50.0 - 70.0
							LYMPHOCYTES	21.3	%	LOW NCS	25.0 - 40.0
							MONOCYTES	6.4	%		2.0 - 14.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	001	1	SCREENING	-7	02APR2009	10:40	EOSINOPHILS	0.5	%		< 4.0
							BASOPHILS	0.2	%		< 1.0
							LUC	0	%		< 4.0
							INR-VALUE	1.02			0.83 - 1.43
			V1 (WEEK 0)	1	09APR2009	10:30	aPTT	36.7	sec		26.0 - 40.0
							QUICK (VENOUS)	97	%		> 70
							ERYTHROCYTES	5.1	/pL		3.8 - 5.3
							HEMOGLOBIN	9	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.46	L/L		0.35 - 0.47
							MCH (HbE)	1.76	fmol		1.74 - 1.99
							MCHC	19.5	mmol/L	LOW NCS	19.9 - 22.9
							MCV	90.2	fL		82.0 - 96.0
							THROMBOCYTES	272	/nL		150 - 400
							LEUKOCYTES	4.9	/nL		4.0 - 9.0
							NEUTROPHILS	76.7	%	HIGH NCS	50.0 - 70.0
							LYMPHOCYTES	17.2	%	LOW NCS	25.0 - 40.0
							MONOCYTES	5.3	%		2.0 - 14.0
							EOSINOPHILS	0.6	%		< 4.0
							BASOPHILS	0.2	%		< 1.0
							LUC	0	%		< 4.0
			V3 (WEEK 12)	90	07JUL2009	8:55	ERYTHROCYTES	4.9	/pL		3.8 - 5.3
							HEMOGLOBIN	8.4	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.45	L/L		0.35 - 0.47

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	001	1	V3 (WEEK 12)	90	07JUL2009	8:55	MCH (HbE)	1.72	fmol	LOW	NCS	1.74 - 1.99
							MCHC	18.5	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	92.8	fL			82.0 - 96.0
							THROMBOCYTES	275	/nL			150 - 400
							LEUKOCYTES	4.8	/nL			4.0 - 9.0
							NEUTROPHILS	62.3	%			50.0 - 70.0
							LYMPHOCYTES	29.5	%			25.0 - 40.0
							MONOCYTES	6.3	%			2.0 - 14.0
							EOSINOPHILS	1.5	%			< 4.0
							BASOPHILS	0.4	%			< 1.0
							LUC	0	%			< 4.0
			V4 (WEEK 24)	162	17SEP2009	11:00	ERYTHROCYTES	5	/pL			3.8 - 5.3
							HEMOGLOBIN	8.9	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.45	L/L			0.35 - 0.47
							MCH (HbE)	1.79	fmol			1.74 - 1.99
							MCHC	19.7	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	91	fL			82.0 - 96.0
							THROMBOCYTES	281	/nL			150 - 400
							LEUKOCYTES	5	/nL			4.0 - 9.0
							NEUTROPHILS	70.5	%	HIGH	NCS	50.0 - 70.0
							LYMPHOCYTES	23.1	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	5.8	%			2.0 - 14.0
							EOSINOPHILS	0.4	%			< 4.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	001	1	V4 (WEEK 24)	162	17SEP2009	11:00	BASOPHILS	0.2	%		< 1.0
			V5 (WEEK 36)	246	10DEC2009	9:10	ERYTHROCYTES	4.9	/pL		3.8 - 5.3
							HEMOGLOBIN	8.9	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.44	L/L		0.35 - 0.47
							MCH (HbE)	1.82	fmol		1.74 - 1.99
							MCHC	20.1	mmol/L		19.9 - 22.9
							MCV	90.4	fL		82.0 - 96.0
							THROMBOCYTES	296	/nL		150 - 400
							LEUKOCYTES	5.5	/nL		4.0 - 9.0
							NEUTROPHILS	63.4	%		50.0 - 70.0
							LYMPHOCYTES	28.5	%		25.0 - 40.0
							MONOCYTES	6.4	%		2.0 - 14.0
							EOSINOPHILS	1.5	%		< 4.0
							BASOPHILS	0.2	%		< 1.0
			V6 (WEEK 52)	365	08APR2010	9:00	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	19.3	mmol/L	LOW NCS	19.8 - 22.3
							MCV	92.3	fL		79.4 - 94.8
							THROMBOCYTES	355	/nL		182 - 369
							LEUKOCYTES	5.8	/nL		4.0 - 10.0
							NEUTROPHILS	61.8	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	001	1	V6 (WEEK 52)	365	08APR2010	9:00	LYMPHOCYTES	30.1	%		19.0 - 52.0
							MONOCYTES	6.5	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
			V7 (WEEK 56)	393	06MAY2010	13:15	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.81	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	90.5	fL		79.4 - 94.8
							THROMBOCYTES	349	/nL		182 - 369
							LEUKOCYTES	8.2	/nL		4.0 - 10.0
							NEUTROPHILS	62.5	%		34.0 - 71.0
							LYMPHOCYTES	29.5	%		19.0 - 52.0
	003	1	SCREENING	-21	07MAY2009	10:10	MONOCYTES	5.9	%		5.0 - 13.0
							EOSINOPHILS	2	%		1.0 - 6.0
							BASOPHILS	0.1	%		< 1.0
							ERYTHROCYTES	4.9	/pL		3.8 - 5.3
							HEMOGLOBIN	9	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.46	L/L		0.35 - 0.47
							MCH (HbE)	1.84	fmol		1.74 - 1.99
							MCHC	19.5	mmol/L	LOW NCS	19.9 - 22.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	003	1	SCREENING	-21	07MAY2009	10:10	MCV	94.7	fL		82.0 - 110
							THROMBOCYTES	253	/nL		150 - 400
							LEUKOCYTES	6.4	/nL		
							NEUTROPHILS	65.2	%		50.0 - 70.0
							LYMPHOCYTES	22.3	%	LOW NCS	25.0 - 40.0
							MONOCYTES	7.5	%		2.0 - 14.0
							EOSINOPHILS	4.8	%	HIGH NCS	< 4.0
							BASOPHILS	0.2	%		< 1.0
							LUC	0	%		< 4.0
							INR-VALUE	1			0.83 - 1.43
							aPTT	29.2	sec		26.0 - 40.0
							QUICK (VENOUS)	120	%		> 70
			V1 (WEEK 0)	1	28MAY2009	11:25	ERYTHROCYTES	4.7	/pL		3.8 - 5.3
							HEMOGLOBIN	8.5	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.43	L/L		0.35 - 0.47
							MCH (HbE)	1.82	fmol		1.74 - 1.99
							MCHC	20	mmol/L		19.9 - 22.9
							MCV	91	fL		82.0 - 96.0
							THROMBOCYTES	275	/nL		150 - 400
							LEUKOCYTES	6.1	/nL		4.0 - 9.0
							NEUTROPHILS	65.4	%		50.0 - 70.0
							LYMPHOCYTES	22.7	%	LOW NCS	25.0 - 40.0
							MONOCYTES	7.2	%		2.0 - 14.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	003	1	V1 (WEEK 0)	1	28MAY2009	11:25	EOSINOPHILS	4.4	%	HIGH NCS	< 4.0
			V3 (WEEK 12)	90	25AUG2009	11:50	BASOPHILS	0.3	%		< 1.0
							LUC	0	%		< 4.0
							ERYTHROCYTES	4.8	/pL		3.8 - 5.3
							HEMOGLOBIN	8.7	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.46	L/L		0.35 - 0.47
							MCH (HbE)	1.8	fmol		1.74 - 1.99
							MCHC	19	mmol/L	LOW NCS	19.9 - 22.9
							MCV	94.8	fL		82.0 - 96.0
							THROMBOCYTES	244	/nL		150 - 400
							LEUKOCYTES	8.5	/nL		4.0 - 9.0
							NEUTROPHILS	72.2	%	HIGH NCS	50.0 - 70.0
							LYMPHOCYTES	18.4	%	LOW NCS	25.0 - 40.0
							MONOCYTES	7.4	%		2.0 - 14.0
							EOSINOPHILS	1.8	%		< 4.0
							BASOPHILS	0.2	%		< 1.0
			V4 (WEEK 24)	169	12NOV2009	10:15	ERYTHROCYTES	5	/pL		3.8 - 5.3
							HEMOGLOBIN	9	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.44	L/L		0.35 - 0.47
							MCH (HbE)	1.82	fmol		1.74 - 1.99
							MCHC	20.5	mmol/L		19.9 - 22.9
							MCV	88.9	fL		82.0 - 96.0
							THROMBOCYTES	256	/nL		150 - 400

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	003	1	V4 (WEEK 24)	169	12NOV2009	10:15	LEUKOCYTES	5.3	/nL		4.0 - 9.0
							NEUTROPHILS	58	%		50.0 - 70.0
							LYMPHOCYTES	29.1	%		25.0 - 40.0
							MONOCYTES	9.3	%		2.0 - 14.0
							EOSINOPHILS	3.4	%		< 4.0
							BASOPHILS	0.2	%		< 1.0
	005	2	SCREENING	-16	19MAY2009	14:00	ERYTHROCYTES	4.4	/pL		3.8 - 5.3
							HEMOGLOBIN	7.8	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.4	L/L		0.35 - 0.47
							MCH (HbE)	1.77	fmol		1.74 - 1.99
							MCHC	19.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	89.8	fL		82.0 - 96.0
							THROMBOCYTES	241	/nL		150 - 400
							LEUKOCYTES	4.7	/nL		4.0 - 9.0
							NEUTROPHILS	58.8	%		50.0 - 70.0
							LYMPHOCYTES	31.4	%		25.0 - 40.0
							MONOCYTES	7.3	%		2.0 - 14.0
							EOSINOPHILS	1.9	%		< 4.0
							BASOPHILS	0.6	%		< 1.0
							LUC	0	%		< 4.0
							INR-VALUE	1.14			0.83 - 1.43
							aPTT	36.8	sec		26.0 - 40.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	005	2	SCREENING	-16	19MAY2009	14:00	QUICK (VENOUS)	83	%		> 70
				1	04JUN2009	8:45	ERYTHROCYTES	4.3	/pL		3.8 - 5.3
			V1 (WEEK 0)				HEMOGLOBIN	7.8	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.4	L/L		0.35 - 0.47
							MCH (HbE)	1.81	fmol		1.74 - 1.99
							MCHC	19.4	mmol/L	LOW NCS	19.9 - 22.9
							MCV	93.2	fL		82.0 - 96.0
							THROMBOCYTES	203	/nL		150 - 400
							LEUKOCYTES	4	/nL		4.0 - 9.0
							NEUTROPHILS	59.1	%		50.0 - 70.0
							LYMPHOCYTES	31.8	%		25.0 - 40.0
							MONOCYTES	6.8	%		2.0 - 14.0
							EOSINOPHILS	1.8	%		< 4.0
							BASOPHILS	0.5	%		< 1.0
							LUC	0	%		< 4.0
			V3 (WEEK 12)	83	25AUG2009	8:30	ERYTHROCYTES	4.5	/pL		3.8 - 5.3
							HEMOGLOBIN	8.1	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.43	L/L		0.39 - 0.55
							MCH (HbE)	1.8	fmol		1.74 - 1.99
							MCHC	18.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	96.4	fL		82.0 - 110
							THROMBOCYTES	219	/nL		150 - 400
							LEUKOCYTES	3.8	/nL		

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	005	2	V3 (WEEK 12)	83	25AUG2009	8:30	NEUTROPHILS	61.7	%		50.0 - 70.0
							LYMPHOCYTES	31.1	%		25.0 - 40.0
							MONOCYTES	5.6	%		2.0 - 14.0
							EOSINOPHILS	1.3	%		< 4.0
							BASOPHILS	0.3	%		< 1.0
			V4 (WEEK 24)	168	18NOV2009	10:00	ERYTHROCYTES	4.3	/pL		3.8 - 5.3
							HEMOGLOBIN	7.7	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.39	L/L		0.39 - 0.55
							MCH (HbE)	1.8	fmol		1.74 - 1.99
							MCHC	19.6	mmol/L	LOW NCS	19.9 - 22.9
							MCV	92	fL		82.0 - 110
							THROMBOCYTES	207	/nL		150 - 400
							LEUKOCYTES	3.7	/nL		
							NEUTROPHILS	63.3	%		50.0 - 70.0
							LYMPHOCYTES	26.8	%		25.0 - 40.0
							MONOCYTES	7.5	%		2.0 - 14.0
							EOSINOPHILS	1.6	%		< 4.0
							BASOPHILS	0.8	%		< 1.0
			V5 (WEEK 36)	258	16FEB2010	9:00	ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	19.7	mmol/L	LOW NCS	19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range	
					Date	Time				High /Low	signi- ficant		
Placebo	005	2	V5 (WEEK 36)	258	16FEB2010	9:00	MCV	90.4	fL			79.4 - 94.8	
							THROMBOCYTES	208	/nL			182 - 369	
							LEUKOCYTES	5	/nL			4.0 - 10.0	
							NEUTROPHILS	67.2	%			34.0 - 71.0	
							LYMPHOCYTES	25.2	%			19.0 - 52.0	
							MONOCYTES	5.6	%			5.0 - 13.0	
							EOSINOPHILS	1.6	%			1.0 - 6.0	
							BASOPHILS	0.4	%			< 1.0	
			V6 (WEEK 52)	364	02JUN2010	9:00	ERYTHROCYTES	4.3	/pL			3.9 - 5.2	
							HEMOGLOBIN	7.8	mmol/L			6.9 - 9.7	
							HEMATOCRIT	0.43	L/L			0.35 - 0.45	
							MCH (HbE)	1.79	fmol			1.59 - 2.00	
							MCHC	18.2	mmol/L	LOW	NCS	19.8 - 22.3	
							MCV	98.8	fL	HIGH	NCS	79.4 - 94.8	
							THROMBOCYTES	240	/nL			182 - 369	
							LEUKOCYTES	5.7	/nL			4.0 - 10.0	
			V7 (WEEK 56)	400	08JUL2010	9:15	NEUTROPHILS	75.1	%		HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	18.5	%		LOW	NCS	19.0 - 52.0
							MONOCYTES	5.7	%				5.0 - 13.0
							EOSINOPHILS	0.5	%		LOW	NCS	1.0 - 6.0
							BASOPHILS	0.2	%				< 1.0
							ERYTHROCYTES	4.2	/pL				3.9 - 5.2
							HEMOGLOBIN	7.5	mmol/L				6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	005	2	V7 (WEEK 56)	400	08JUL2010	9:15	HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.77	fmol		1.59 - 2.00
							MCHC	17.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	100.5	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	222	/nL		182 - 369
							LEUKOCYTES	5.7	/nL		4.0 - 10.0
							NEUTROPHILS	70.6	%		34.0 - 71.0
							LYMPHOCYTES	22.2	%		19.0 - 52.0
							MONOCYTES	5.4	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
	009	1	SCREENING	-33	06AUG2009	11:45	ERYTHROCYTES	4.7	/pL		3.8 - 5.3
							HEMOGLOBIN	8.2	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.44	L/L		0.35 - 0.47
							MCH (HbE)	1.75	fmol		1.74 - 1.99
							MCHC	18.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	93.4	fL		82.0 - 96.0
							THROMBOCYTES	254	/nL		150 - 400
							LEUKOCYTES	5.7	/nL		4.0 - 9.0
							NEUTROPHILS	56.7	%		50.0 - 70.0
							LYMPHOCYTES	31.6	%		25.0 - 40.0
							MONOCYTES	9.6	%		2.0 - 14.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low	ficant range
Placebo	009	1	SCREENING	-33	06AUG2009	11:45	EOSINOPHILS	1.4	%		< 4.0
							BASOPHILS	0.7	%		< 1.0
							INR-VALUE	1.02			0.83 - 1.43
							aPTT	34.8	sec		26.0 - 40.0
			V1 (WEEK 0)	1	08SEP2009	9:10	QUICK (VENOUS)	96	%		> 70
							ERYTHROCYTES	4.9	/pL		3.8 - 5.3
							HEMOGLOBIN	8.6	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.47
							MCH (HbE)	1.73	fmol	LOW NCS	1.74 - 1.99
							MCHC	17.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	98	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	260	/nL		150 - 400
							LEUKOCYTES	5.2	/nL		4.0 - 9.0
							NEUTROPHILS	60.4	%		50.0 - 70.0
							LYMPHOCYTES	28.4	%		25.0 - 40.0
							MONOCYTES	8.3	%		2.0 - 14.0
							EOSINOPHILS	1.9	%		< 4.0
							BASOPHILS	1	%	HIGH NCS	< 1.0
			V3 (WEEK 12)	94	10DEC2009	9:40	ERYTHROCYTES	4.8	/pL		3.8 - 5.3
							HEMOGLOBIN	8.7	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.43	L/L		0.35 - 0.47
							MCH (HbE)	1.82	fmol		1.74 - 1.99
							MCHC	20	mmol/L		19.9 - 22.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	009	1	V3 (WEEK 12)	94	10DEC2009	9:40	MCV	90.6	fL		82.0 - 96.0
							THROMBOCYTES	259	/nL		150 - 400
							LEUKOCYTES	6.3	/nL		4.0 - 9.0
							NEUTROPHILS	55.6	%		50.0 - 70.0
							LYMPHOCYTES	27.9	%		25.0 - 40.0
							MONOCYTES	12.9	%		2.0 - 14.0
							EOSINOPHILS	3	%		< 4.0
							BASOPHILS	0.6	%		< 1.0
			V4 (WEEK 24)	178	04MAR2010	12:50	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	8.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L	LOW NCS	19.8 - 22.3
							MCV	90.6	fL		79.4 - 94.8
							THROMBOCYTES	264	/nL		182 - 369
							LEUKOCYTES	7.7	/nL		4.0 - 10.0
							NEUTROPHILS		%		34.0 - 71.0
							NEUTROPHILS	50	%		34 - 71
							LYMPHOCYTES	23	%	LOW NCS	25 - 40
							MONOCYTES	22	%	HIGH NCS	4 - 11
							EOSINOPHILS	1	%		< 4
							BASOPHILS	4	%	HIGH NCS	< 1
			V5 (WEEK 36)	246	11MAY2010	10:20	ERYTHROCYTES	4.8	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	009	1	V5 (WEEK 36)	246	11MAY2010	10:20	HEMOGLOBIN	8.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.43	L/L			0.35 - 0.45
							MCH (HbE)	1.77	fmol			1.59 - 2.00
							MCHC	19.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	90.1	fL			79.4 - 94.8
							THROMBOCYTES	286	/nL			182 - 369
							LEUKOCYTES	7.1	/nL			4.0 - 10.0
							NEUTROPHILS	73.4	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	17.4	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	8.1	%			5.0 - 13.0
							EOSINOPHILS	0.4	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.7	%			< 1.0
			V6 (WEEK 52)	361	03SEP2010	10:15	ERYTHROCYTES	4.7	/pL			3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.78	fmol			1.59 - 2.00
							MCHC	17.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	100.2	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	265	/nL			182 - 369
							LEUKOCYTES	5.7	/nL			4.0 - 10.0
							NEUTROPHILS	72.3	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	19.4	%			19.0 - 52.0
							MONOCYTES	6.7	%			5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	009	1	V6 (WEEK 52)	361	03SEP2010	10:15	EOSINOPHILS	0.9	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.7	%			< 1.0
		1	V7 (WEEK 56)	389	01OCT2010	9:15	ERYTHROCYTES	4.6	/pL			3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.78	fmol			1.59 - 2.00
							MCHC	17.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	100.2	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	248	/nL			182 - 369
							LEUKOCYTES	4.6	/nL			4.0 - 10.0
							NEUTROPHILS	61.1	%			34.0 - 71.0
							LYMPHOCYTES	25.6	%			19.0 - 52.0
							MONOCYTES	10.6	%			5.0 - 13.0
							EOSINOPHILS	2	%			1.0 - 6.0
							BASOPHILS	0.7	%			< 1.0
	011	1	SCREENING	-21	05NOV2009	13:10	ERYTHROCYTES	4.6	/pL			3.8 - 5.3
							HEMOGLOBIN	8.6	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.42	L/L			0.39 - 0.55
							MCH (HbE)	1.87	fmol			1.74 - 1.99
							MCHC	20.6	mmol/L			19.9 - 22.9
							MCV	91.1	fL			82.0 - 110
							THROMBOCYTES	246	/nL			150 - 400

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	011	1	SCREENING	-21	05NOV2009	13:10	LEUKOCYTES	7.5	/nL		
							NEUTROPHILS	52.6	%		50.0 - 70.0
							LYMPHOCYTES	36.2	%		25.0 - 40.0
							MONOCYTES	9.6	%		2.0 - 14.0
							EOSINOPHILS	1.3	%		< 4.0
							BASOPHILS	0.3	%		< 1.0
							INR-VALUE	0.97			0.83 - 1.43
							aPTT	37.9	sec		26.0 - 40.0
							QUICK (VENOUS)	105	%		> 70
			V1 (WEEK 0)	1	26NOV2009	10:25	ERYTHROCYTES	4.9	/pL		3.8 - 5.3
							HEMOGLOBIN	9.1	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.44	L/L		0.39 - 0.55
							MCH (HbE)	1.87	fmol		1.74 - 1.99
							MCHC	20.8	mmol/L		19.9 - 22.9
							MCV	89.9	fL		82.0 - 110
							THROMBOCYTES	261	/nL		150 - 400
							LEUKOCYTES	10.2	/nL		
							NEUTROPHILS	61.8	%		50.0 - 70.0
							LYMPHOCYTES	29.5	%		25.0 - 40.0
							MONOCYTES	7.6	%		2.0 - 14.0
							EOSINOPHILS	0.9	%		< 4.0
							BASOPHILS	0.2	%		< 1.0
			V3 (WEEK 12)	85	18FEB2010	9:05	ERYTHROCYTES	4.8	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	011	1	V3 (WEEK 12)	85	18FEB2010	9:05	HEMOGLOBIN	8.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	89.7	fL		79.4 - 94.8
							THROMBOCYTES	235	/nL		182 - 369
							LEUKOCYTES	6.2	/nL		4.0 - 10.0
							NEUTROPHILS	44.2	%		34.0 - 71.0
							LYMPHOCYTES	43.2	%		19.0 - 52.0
							MONOCYTES	10.9	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V4 (WEEK 24)	162	06MAY2010	13:30	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	9.3	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.83	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	88.8	fL		79.4 - 94.8
							THROMBOCYTES	252	/nL		182 - 369
							LEUKOCYTES	6.6	/nL		4.0 - 10.0
							NEUTROPHILS	49.3	%		34.0 - 71.0
							LYMPHOCYTES	39	%		19.0 - 52.0
							MONOCYTES	10	%		5.0 - 13.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	011	1	V4 (WEEK 24)	162	06MAY2010	13:30	EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V5 (WEEK 36)	253	05AUG2010	12:10	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.92	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	91.2	fL		79.4 - 94.8
							THROMBOCYTES	244	/nL		182 - 369
							LEUKOCYTES	6.1	/nL		4.0 - 10.0
							NEUTROPHILS	48.2	%		34.0 - 71.0
							LYMPHOCYTES	42.3	%		19.0 - 52.0
							MONOCYTES	8	%		5.0 - 13.0
							EOSINOPHILS	1.3	%		1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
			V6 (WEEK 52)	366	26NOV2010	10:10	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	94	fL		79.4 - 94.8
							THROMBOCYTES	232	/nL		182 - 369
							LEUKOCYTES	7	/nL		4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	011	1	V6 (WEEK 52)	366	26NOV2010	10:10	NEUTROPHILS	61.3	%		34.0 - 71.0
							LYMPHOCYTES	30	%		19.0 - 52.0
							MONOCYTES	7	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V7 (WEEK 56)	397	27DEC2010	12:30	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	89.2	fL		79.4 - 94.8
							THROMBOCYTES	253	/nL		182 - 369
							LEUKOCYTES	7	/nL		4.0 - 10.0
							NEUTROPHILS	55.9	%		34.0 - 71.0
							LYMPHOCYTES	33.8	%		19.0 - 52.0
							MONOCYTES	8.6	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
	013	4	SCREENING	-30	17AUG2009	10:00	ERYTHROCYTES	3.9	/pL		3.8 - 5.3
							HEMOGLOBIN	7.9	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.43	L/L		0.35 - 0.47
							MCH (HbE)	2.02	fmol	HIGH NCS	1.74 - 1.99

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	013	4	SCREENING	-30	17AUG2009	10:00	MCHC	18.4	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	109.5	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	219	/nL			150 - 400
							LEUKOCYTES	6.1	/nL			4.0 - 9.0
							NEUTROPHILS	68.9	%			50.0 - 70.0
							LYMPHOCYTES	20.8	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	7.2	%			2.0 - 14.0
							EOSINOPHILS	2.6	%			< 4.0
							BASOPHILS	0.5	%			< 1.0
							INR-VALUE	1.03				0.83 - 1.43
							aPTT	31.1	sec			26.0 - 40.0
							QUICK (VENOUS)	95	%			> 70
			V1 (WEEK 0)	1	16SEP2009	9:00	ERYTHROCYTES	3.6	/pL	LOW	NCS	3.8 - 5.3
							HEMOGLOBIN	7.1	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.37	L/L			0.35 - 0.47
							MCH (HbE)	1.99	fmol			1.74 - 1.99
							MCHC	19.2	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	103.9	fL	HIGH	NCS	82.0 - 96.0
							THROMBOCYTES	229	/nL			150 - 400
							LEUKOCYTES	3.8	/nL	LOW	NCS	4.0 - 9.0
							NEUTROPHILS	65.1	%			50.0 - 70.0
							LYMPHOCYTES	25	%			25.0 - 40.0
							MONOCYTES	5.6	%			2.0 - 14.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	013	4	V1 (WEEK 0)	1	16SEP2009	9:00	EOSINOPHILS	3.5	%		< 4.0
							BASOPHILS	0.8	%		< 1.0
			V3 (WEEK 12)	85	09DEC2009	10:00	ERYTHROCYTES	3.8	/pL		3.8 - 5.3
							HEMOGLOBIN	7.5	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.38	L/L		0.35 - 0.47
							MCH (HbE)	1.98	fmol		1.74 - 1.99
							MCHC	19.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	100.5	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	248	/nL		150 - 400
							LEUKOCYTES	3.9	/nL	LOW NCS	4.0 - 9.0
							NEUTROPHILS	58.7	%		50.0 - 70.0
							LYMPHOCYTES	27.8	%		25.0 - 40.0
							MONOCYTES	9.4	%		2.0 - 14.0
							EOSINOPHILS	3.1	%		< 4.0
							BASOPHILS	1	%	HIGH NCS	< 1.0
			V4 (WEEK 24)	170	04MAR2010	10:00	ERYTHROCYTES	3.9	/pL		3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45
							MCH (HbE)	1.99	fmol		1.59 - 2.00
							MCHC	19.9	mmol/L		19.8 - 22.3
							MCV	100	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	250	/nL		182 - 369
							LEUKOCYTES	3.7	/nL	LOW NCS	4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	013	4	V4 (WEEK 24)	170	04MAR2010	10:00	NEUTROPHILS	65.5	%		34.0 - 71.0
							LYMPHOCYTES	24.8	%		19.0 - 52.0
							MONOCYTES	6.5	%		5.0 - 13.0
							EOSINOPHILS	2.4	%		1.0 - 6.0
							BASOPHILS	0.8	%		< 1.0
			V5 (WEEK 36)	247	20MAY2010	10:25	ERYTHROCYTES	3.9	/pL		3.9 - 5.2
							HEMOGLOBIN	7.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45
							MCH (HbE)	2	fmol		1.59 - 2.00
							MCHC	19.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	101.8	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	239	/nL		182 - 369
							LEUKOCYTES	3.5	/nL	LOW NCS	4.0 - 10.0
							NEUTROPHILS	63.1	%		34.0 - 71.0
							LYMPHOCYTES	26.8	%		19.0 - 52.0
							MONOCYTES	6.8	%		5.0 - 13.0
							EOSINOPHILS	2.5	%		1.0 - 6.0
							BASOPHILS	0.8	%		< 1.0
			V6 (WEEK 52)	366	16SEP2010	11:00	ERYTHROCYTES	3.9	/pL		3.9 - 5.2
							HEMOGLOBIN	8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	2.05	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	013	4	V6 (WEEK 52)	366	16SEP2010	11:00	MCV	101	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	222	/nL			182 - 369
							LEUKOCYTES	4.1	/nL			4.0 - 10.0
							NEUTROPHILS	66.6	%			34.0 - 71.0
							LYMPHOCYTES	24.2	%			19.0 - 52.0
							MONOCYTES	6.3	%			5.0 - 13.0
							EOSINOPHILS	2.2	%			1.0 - 6.0
							BASOPHILS	0.7	%			< 1.0
			V7 (WEEK 56)	400	20OCT2010	11:45	ERYTHROCYTES	3.8	/pL	LOW	NCS	3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.39	L/L			0.35 - 0.45
							MCH (HbE)	2.02	fmol			1.59 - 2.00
							MCHC	20.1	mmol/L			19.8 - 22.3
							MCV	100.5	fL			79.4 - 94.8
							THROMBOCYTES	218	/nL			182 - 369
							LEUKOCYTES	3.9	/nL			4.0 - 10.0
							NEUTROPHILS	62.7	%			34.0 - 71.0
							LYMPHOCYTES	27.9	%			19.0 - 52.0
							MONOCYTES	6.6	%			5.0 - 13.0
							EOSINOPHILS	2.3	%			1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0
	016	4	SCREENING	-28	01FEB2010	10:00	ERYTHROCYTES	5.4	/pL			4.6 - 6.1

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	016	4	SCREENING	-28	01FEB2010	10:00	HEMOGLOBIN	10.2	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.89	fmol		1.59 - 2.00
							MCHC	21.9	mmol/L		19.8 - 22.3
							MCV	86.4	fL		79.0 - 92.2
							THROMBOCYTES	170	/nL		163 - 337
							LEUKOCYTES	5.8	/nL		4.2 - 9.1
							NEUTROPHILS	60.9	%		34.0 - 68.0
							LYMPHOCYTES	27.1	%		22.0 - 53.0
							MONOCYTES	9.1	%		5.0 - 12.0
							EOSINOPHILS	2.4	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
							INR-VALUE	1.11			0.83 - 1.43
							aPTT	46.1	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	85	%		> 70
			V1 (WEEK 0)	1	01MAR2010	10:00	ERYTHROCYTES	5.2	/pL		4.6 - 6.1
							HEMOGLOBIN	9.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	87.9	fL		79.0 - 92.2
							THROMBOCYTES	175	/nL		163 - 337
							LEUKOCYTES	5.2	/nL		4.2 - 9.1

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	016	4	V1 (WEEK 0)	1	01MAR2010	10:00	NEUTROPHILS	53.8	%		34.0 - 68.0
							LYMPHOCYTES	34	%		22.0 - 53.0
							MONOCYTES	8.9	%		5.0 - 12.0
							EOSINOPHILS	2.7	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
			V3 (WEEK 12)	80	19MAY2010	9:15	ERYTHROCYTES	5.3	/pL		4.6 - 6.1
							HEMOGLOBIN	9.8	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.86	fmol		1.59 - 2.00
							MCHC	21.5	mmol/L		19.8 - 22.3
							MCV	86.5	fL		79.0 - 92.2
							THROMBOCYTES	163	/nL		163 - 337
							LEUKOCYTES	4.7	/nL		4.2 - 9.1
							NEUTROPHILS	52.2	%		34.0 - 68.0
							LYMPHOCYTES	32.4	%		22.0 - 53.0
							MONOCYTES	10.9	%		5.0 - 12.0
							EOSINOPHILS	4.1	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V4 (WEEK 24)	162	09AUG2010	10:20	ERYTHROCYTES	5.3	/pL		4.6 - 6.1
							HEMOGLOBIN	9.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.49	L/L		0.40 - 0.50
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	016	4	V4 (WEEK 24)	162	09AUG2010	10:20	MCV	92.4	fL	HIGH NCS	79.0 - 92.2	
							THROMBOCYTES	210	/nL		163 - 337	
							LEUKOCYTES	5.4	/nL		4.2 - 9.1	
							NEUTROPHILS	59.1	%		34.0 - 68.0	
							LYMPHOCYTES	29.4	%		22.0 - 53.0	
							MONOCYTES	9.1	%		5.0 - 12.0	
							EOSINOPHILS	2	%		1.0 - 7.0	
							BASOPHILS	0.4	%		< 1.0	
			V5 (WEEK 36)	253	08NOV2010	9:45	ERYTHROCYTES	5.2	/pL	4.6 - 6.1		
							HEMOGLOBIN	9.7	mmol/L	8.5 - 10.9		
							HEMATOCRIT	0.45	L/L	0.40 - 0.50		
							MCH (HbE)	1.88	fmol	1.59 - 2.00		
							MCHC	21.6	mmol/L	19.8 - 22.3		
							MCV	87.4	fL	79.0 - 92.2		
							THROMBOCYTES	185	/nL	163 - 337		
							LEUKOCYTES	5.5	/nL	4.2 - 9.1		
			V6 (WEEK 52)	365	28FEB2011	10:30	NEUTROPHILS	63	%	34.0 - 68.0		
							LYMPHOCYTES	23.8	%	22.0 - 53.0		
							MONOCYTES	8.7	%	5.0 - 12.0		
							EOSINOPHILS	4	%	1.0 - 7.0		
							BASOPHILS	0.5	%	< 1.0		
							ERYTHROCYTES	5.2	/pL	4.6 - 6.1		
							HEMOGLOBIN	9.7	mmol/L	8.5 - 10.9		

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	016	4	V6 (WEEK 52)	365	28FEB2011	10:30	HEMATOCRIT	0.51	L/L	HIGH	NCS	0.40 - 0.50
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	19	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	96.9	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	177	/nL			163 - 337
							LEUKOCYTES	7.3	/nL			4.2 - 9.1
							NEUTROPHILS	83.3	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	12	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	3.7	%	LOW	NCS	5.0 - 12.0
							EOSINOPHILS	0.7	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.3	%			< 1.0
			V7 (WEEK 56)	403	07APR2011	11:00	ERYTHROCYTES	5.3	/pL			4.6 - 6.1
							HEMOGLOBIN	9.9	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.47	L/L			0.40 - 0.50
							MCH (HbE)	1.87	fmol			1.59 - 2.00
							MCHC	21.3	mmol/L			19.8 - 22.3
							MCV	87.6	fL			79.0 - 92.2
							THROMBOCYTES	170	/nL			163 - 337
							LEUKOCYTES	4.5	/nL			4.2 - 9.1
							NEUTROPHILS	60	%			34.0 - 68.0
							LYMPHOCYTES	28.5	%			22.0 - 53.0
							MONOCYTES	8.3	%			5.0 - 12.0
							EOSINOPHILS	2.5	%			1.0 - 7.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	016	4	V7 (WEEK 56)	403	07APR2011	11:00	BASOPHILS	0.7	%		< 1.0
	018	5	SCREENING	-20	03NOV2009	13:15	ERYTHROCYTES	4.5	/pL		3.8 - 5.3
							HEMOGLOBIN	8	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.41	L/L		0.35 - 0.47
							MCH (HbE)	1.77	fmol		1.74 - 1.99
							MCHC	19.7	mmol/L	LOW NCS	19.9 - 22.9
							MCV	89.8	fL		82.0 - 110
							THROMBOCYTES	190	/nL		150 - 400
							LEUKOCYTES	5.6	/nL		
							NEUTROPHILS	46.4	%	LOW NCS	50.0 - 70.0
							LYMPHOCYTES	39.9	%		25.0 - 40.0
							MONOCYTES	9	%		2.0 - 14.0
							EOSINOPHILS	4.3	%	HIGH NCS	< 4.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	1.03			0.83 - 1.43
							aPTT	47.2	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	95	%		> 70
			V1 (WEEK 0)	1	23NOV2009	13:00	ERYTHROCYTES	4.4	/pL		3.8 - 5.3
							HEMOGLOBIN	7.9	mmol/L		6.8 - 10.2
							HEMATOCRIT	0.39	L/L		0.35 - 0.47
							MCH (HbE)	1.79	fmol		1.74 - 1.99
							MCHC	20	mmol/L		19.9 - 22.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	018	5	V1 (WEEK 0)	1	23NOV2009	13:00	MCV	89.3	fL		82.0 - 96.0
							THROMBOCYTES	193	/nL		150 - 400
							LEUKOCYTES	5.7	/nL		4.0 - 9.0
							NEUTROPHILS	51.3	%		50.0 - 70.0
							LYMPHOCYTES	38.1	%		25.0 - 40.0
							MONOCYTES	7.7	%		2.0 - 14.0
							EOSINOPHILS	2.5	%		< 4.0
			V3 (WEEK 12)	86	16FEB2010	12:45	BASOPHILS	0.4	%		< 1.0
							ERYTHROCYTES	4.2	/pL		3.9 - 5.2
							HEMOGLOBIN	7.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.38	L/L		0.35 - 0.45
							MCH (HbE)	1.84	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	90.7	fL		79.4 - 94.8
			V4 (WEEK 24)	170	11MAY2010	9:00	THROMBOCYTES	174	/nL	LOW NCS	182 - 369
							LEUKOCYTES	4.9	/nL		4.0 - 10.0
							NEUTROPHILS	53.9	%		34.0 - 71.0
							LYMPHOCYTES	31.8	%		19.0 - 52.0
							MONOCYTES	10.2	%		5.0 - 13.0
							EOSINOPHILS	3.7	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
							ERYTHROCYTES	4.1	/pL		3.9 - 5.2
							HEMOGLOBIN	7.5	mmol/L		6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	018	5	V4 (WEEK 24)	170	11MAY2010	9:00	HEMATOCRIT	0.37	L/L			0.35 - 0.45
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	20.3	mmol/L			19.8 - 22.3
							MCV	90.9	fL			79.4 - 94.8
							THROMBOCYTES	175	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	5.2	/nL			4.0 - 10.0
							NEUTROPHILS	45.7	%			34.0 - 71.0
							LYMPHOCYTES	36.1	%			19.0 - 52.0
							MONOCYTES	11.4	%			5.0 - 13.0
							EOSINOPHILS	6.2	%	HIGH	NCS	1.0 - 6.0
							BASOPHILS	0.6	%			< 1.0
			V5 (WEEK 36)	247	27JUL2010	9:00	ERYTHROCYTES	4.1	/pL			3.9 - 5.2
							HEMOGLOBIN	7.5	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.39	L/L			0.35 - 0.45
							MCH (HbE)	1.82	fmol			1.59 - 2.00
							MCHC	19.3	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	94.2	fL			79.4 - 94.8
							THROMBOCYTES	160	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	4.7	/nL			4.0 - 10.0
							NEUTROPHILS	41.7	%			34.0 - 71.0
							LYMPHOCYTES	40.8	%			19.0 - 52.0
							MONOCYTES	12.2	%			5.0 - 13.0
							EOSINOPHILS	4.9	%			1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	018	5	V5 (WEEK 36)	247	27JUL2010	9:00	BASOPHILS	0.4	%		< 1.0
			V6 (WEEK 52)	366	23NOV2010	9:20	ERYTHROCYTES	4.1	/pL		3.9 - 5.2
							HEMOGLOBIN	7.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.38	L/L		0.35 - 0.45
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	91.3	fL		79.4 - 94.8
							THROMBOCYTES	177	/nL	LOW NCS	182 - 369
							LEUKOCYTES	4.1	/nL		4.0 - 10.0
							NEUTROPHILS	53	%		34.0 - 71.0
							LYMPHOCYTES	32.7	%		19.0 - 52.0
							MONOCYTES	10.7	%		5.0 - 13.0
							EOSINOPHILS	3.1	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V7 (WEEK 56)	387	14DEC2010	8:50	ERYTHROCYTES	4	/pL		3.9 - 5.2
							HEMOGLOBIN	7.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.37	L/L		0.35 - 0.45
							MCH (HbE)	1.83	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	91.6	fL		79.4 - 94.8
							THROMBOCYTES	150	/nL	LOW NCS	182 - 369
							LEUKOCYTES	4.8	/nL		4.0 - 10.0
							NEUTROPHILS	56.2	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	018	5	V7 (WEEK 56)	387	14DEC2010	8:50	LYMPHOCYTES	27.2	%	HIGH NCS	19.0 - 52.0
							MONOCYTES	13.3	%		5.0 - 13.0
							EOSINOPHILS	3.1	%		1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
	020	5	SCREENING	-26	27JAN2010	15:30	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.4	L/L		0.40 - 0.50
							MCH (HbE)	1.86	fmol		1.59 - 2.00
							MCHC	21.8	mmol/L		19.8 - 22.3
							MCV	85.3	fL		79.0 - 92.2
							THROMBOCYTES	187	/nL		163 - 337
							LEUKOCYTES	6.8	/nL		4.2 - 9.1
							NEUTROPHILS	41	%		34.0 - 68.0
							LYMPHOCYTES	47.1	%		22.0 - 53.0
							MONOCYTES	8.4	%		5.0 - 12.0
							EOSINOPHILS	3.1	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	1.08			0.83 - 1.43
							aPTT	33.3	sec		26.0 - 40.0
							QUICK (VENOUS)	88	%		> 70
			V1 (WEEK 0)	1	22FEB2010	13:20	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	020	5	V1 (WEEK 0)	1	22FEB2010	13:20	HEMATOCRIT	0.41	L/L		0.40 - 0.50
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	21.6	mmol/L		19.8 - 22.3
							MCV	86.7	fL		79.0 - 92.2
							THROMBOCYTES	218	/nL		163 - 337
							LEUKOCYTES	5.6	/nL		4.2 - 9.1
							NEUTROPHILS	55.9	%		34.0 - 68.0
							LYMPHOCYTES	34.3	%		22.0 - 53.0
							MONOCYTES	7.7	%		5.0 - 12.0
							EOSINOPHILS	1.6	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
	024	4	SCREENING	-31	16JUL2010	9:30	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	8.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.52	L/L	HIGH NCS	0.40 - 0.50
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	16.3	mmol/L	LOW NCS	19.8 - 22.3
							MCV	110.1	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	165	/nL		163 - 337
							LEUKOCYTES	6	/nL		4.2 - 9.1
							NEUTROPHILS	70.2	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	22.2	%		22.0 - 53.0
							MONOCYTES	5.5	%		5.0 - 12.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	024	4	SCREENING	-31	16JUL2010	9:30	EOSINOPHILS	1.8	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
							INR-VALUE	1.26			0.83 - 1.43
							aPTT	34.5	sec		26.0 - 40.0
							QUICK (VENOUS)	72	%		> 70
			V1 (WEEK 0)	1	16AUG2010	9:30	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	8.4	mmol/L	LOW NCS	8.5 - 10.9
							HEMATOCRIT	0.43	L/L		0.40 - 0.50
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	19.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	91.4	fL		79.0 - 92.2
							THROMBOCYTES	202	/nL		163 - 337
							LEUKOCYTES	6.2	/nL		4.2 - 9.1
							NEUTROPHILS	69.9	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	20.8	%	LOW NCS	22.0 - 53.0
							MONOCYTES	7.2	%		5.0 - 12.0
							EOSINOPHILS	1.6	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
			V3 (WEEK 12)	87	10NOV2010	10:20	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.77	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.	Reference range
					Date	Time				High signi- /Low ficant	
Placebo	024	4	V3 (WEEK 12)	87	10NOV2010	10:20	MCV	86.9	fL		79.0 - 92.2
							THROMBOCYTES	172	/nL		163 - 337
							LEUKOCYTES	6.2	/nL		4.2 - 9.1
							NEUTROPHILS	66.3	%		34.0 - 68.0
							LYMPHOCYTES	23.3	%		22.0 - 53.0
							MONOCYTES	8.2	%		5.0 - 12.0
							EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
			V4 (WEEK 24)	171	02FEB2011	9:30	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.76	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	88	fL		79.0 - 92.2
							THROMBOCYTES	194	/nL		163 - 337
							LEUKOCYTES	6.2	/nL		4.2 - 9.1
			V5 (WEEK 36)	246	18APR2011	10:00	NEUTROPHILS	65	%		34.0 - 68.0
							LYMPHOCYTES	22.5	%		22.0 - 53.0
							MONOCYTES	9.1	%		5.0 - 12.0
							EOSINOPHILS	2.6	%		1.0 - 7.0
							BASOPHILS	0.8	%		< 1.0
							ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	8.9	mmol/L		8.5 - 10.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	024	4	V5 (WEEK 36)	246	18APR2011	10:00	HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	19.9	mmol/L		19.8 - 22.3
							MCV	90.3	fL		79.0 - 92.2
							THROMBOCYTES	206	/nL		163 - 337
							LEUKOCYTES	6.3	/nL		4.2 - 9.1
							NEUTROPHILS	69.3	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	20.7	%	LOW NCS	22.0 - 53.0
							MONOCYTES	7.4	%		5.0 - 12.0
							EOSINOPHILS	2.1	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
			V6 (WEEK 52)	358	08AUG2011	9:30	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	8.5	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW	19.8 - 22.3
							MCV	91.6	fL		79.0 - 92.2
							THROMBOCYTES	181	/nL		163 - 337
							LEUKOCYTES	5.5	/nL		4.2 - 9.1
							NEUTROPHILS	62.9	%		34.0 - 68.0
							LYMPHOCYTES	26.2	%		22.0 - 53.0
							MONOCYTES	7.1	%		5.0 - 12.0
							EOSINOPHILS	3.3	%		1.0 - 7.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	024	4	V6 (WEEK 52)	358	08AUG2011	9:30	BASOPHILS	0.5	%		< 1.0
			V7 (WEEK 56)	393	12SEP2011	11:40	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	8.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	91.2	fL		79.0 - 92.2
							THROMBOCYTES	174	/nL		163 - 337
							LEUKOCYTES	5.8	/nL		4.2 - 9.1
							NEUTROPHILS	62	%		34.0 - 68.0
							LYMPHOCYTES	27.2	%		22.0 - 53.0
							MONOCYTES	7.7	%		5.0 - 12.0
							EOSINOPHILS	2.6	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
	028	20	SCREENING	-8	18NOV2010	10:20	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	92.1	fL		79.4 - 94.8
							THROMBOCYTES	183	/nL		182 - 369
							LEUKOCYTES	3.7	/nL	LOW NCS	4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	028	20	SCREENING	-8	18NOV2010	10:20	NEUTROPHILS	36.5	%		34.0 - 71.0
							LYMPHOCYTES	41.1	%		19.0 - 52.0
							MONOCYTES	21.1	%	HIGH NCS	5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
							INR-VALUE	1.12			0.83 - 1.43
							aPTT	34.5	sec		26.0 - 40.0
							QUICK (VENOUS)	84	%		> 70
			V1 (WEEK 0)	1	26NOV2010	9:15	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	93.8	fL		79.4 - 94.8
							THROMBOCYTES	170	/nL	LOW NCS	182 - 369
							LEUKOCYTES	3	/nL	LOW NCS	4.0 - 10.0
							NEUTROPHILS	5	%	LOW NCS	34 - 71
							LYMPHOCYTES	75	%	HIGH NCS	25 - 40
							MONOCYTES	16	%	HIGH NCS	4 - 11
							EOSINOPHILS	0	%		< 4
							BASOPHILS	4	%	HIGH NCS	< 1
			V3 (WEEK 12)	89	22FEB2011	10:20	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	028	20	V3 (WEEK 12)	89	22FEB2011	10:20	HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.84	fmol			1.59 - 2.00
							MCHC	19.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	93.7	fL			79.4 - 94.8
							THROMBOCYTES	175	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	3.9	/nL	LOW	NCS	4.0 - 10.0
							NEUTROPHILS	35.7	%			34.0 - 71.0
							LYMPHOCYTES	45.5	%			19.0 - 52.0
							MONOCYTES	17.5	%	HIGH	CS	5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.5	%		NCS	< 1.0
			V4 (WEEK 24)	180	24MAY2011	10:05	ERYTHROCYTES	4.6	/pL			3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.81	fmol			1.59 - 2.00
							MCHC	18.9	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	95.7	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	176	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	3.5	/nL	LOW	NCS	4.0 - 10.0
							NEUTROPHILS	35	%			34.0 - 71.0
							LYMPHOCYTES	37.3	%			19.0 - 52.0
							MONOCYTES	25.1	%	HIGH	NCS	5.0 - 13.0
							EOSINOPHILS	2	%			1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant range	
Placebo	028	20	V4 (WEEK 24)	180	24MAY2011	10:05	BASOPHILS	0.6	%		< 1.0
			V5 (WEEK 36)	273	25AUG2011	10:45	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.84	fmol		1.59 - 2.00
							MCHC	18.3	mmol/L	LOW NCS	19.8 - 22.3
							MCV	100.2	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	136	/nL	LOW NCS	182 - 369
							LEUKOCYTES	3.9	/nL	LOW NCS	4.0 - 10.0
							NEUTROPHILS	34.4	%		34.0 - 71.0
							LYMPHOCYTES	47.2	%		19.0 - 52.0
							MONOCYTES	17.6	%	HIGH NCS	5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0	%		< 1.0
			V6 (WEEK 52)	364	24NOV2011	8:09	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	92.3	fL		79.4 - 94.8
							THROMBOCYTES	171	/nL	LOW NCS	182 - 369
							LEUKOCYTES	3.4	/nL	LOW NCS	4.0 - 10.0
							NEUTROPHILS	36.2	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant		Reference range
					Date	Time						
Placebo	028	20	V6 (WEEK 52)	364	24NOV2011	8:09	LYMPHOCYTES	42.1	%			19.0 - 52.0
							MONOCYTES	20.5	%	HIGH	NCS	5.0 - 13.0
							EOSINOPHILS	0.9	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
							ERYTHROCYTES	4.7	/pL			3.9 - 5.2
			V7 (WEEK 56)	390	20DEC2011	10:15	HEMOGLOBIN	8.7	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.43	L/L			0.35 - 0.45
							MCH (HbE)	1.84	fmol			1.59 - 2.00
							MCHC	20.2	mmol/L			19.8 - 22.3
							MCV	91.6	fL			79.4 - 94.8
							THROMBOCYTES	181	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	4.1	/nL			4.0 - 10.0
							NEUTROPHILS	33.6	%	LOW	NCS	34.0 - 71.0
							LYMPHOCYTES	42.2	%			19.0 - 52.0
							MONOCYTES	23	%	HIGH	NCS	5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0
	029	8	SCREENING	-3	26JAN2010	9:45	ERYTHROCYTES	4.7	/pL			3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.84	fmol			1.59 - 2.00
							MCHC	19.8	mmol/L			19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	029	8	SCREENING	-3	26JAN2010	9:45	MCV	92.6	fL		79.4 - 94.8
							THROMBOCYTES	261	/nL		182 - 369
							LEUKOCYTES	5.1	/nL		4.0 - 10.0
							NEUTROPHILS	56.5	%		34.0 - 71.0
							LYMPHOCYTES	18.8	%	LOW NCS	19.0 - 52.0
							MONOCYTES	8.6	%		5.0 - 13.0
							EOSINOPHILS	15.1	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	1	%	HIGH NCS	< 1.0
							INR-VALUE	1.03			0.83 - 1.43
							aPTT	34.8	sec		26.0 - 40.0
							QUICK (VENOUS)	96	%		> 70
			V1 (WEEK 0)	1	29JAN2010	10:00	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	19	mmol/L	LOW NCS	19.8 - 22.3
							MCV	95.6	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	273	/nL		182 - 369
							LEUKOCYTES	6.3	/nL		4.0 - 10.0
							NEUTROPHILS	66.9	%		34.0 - 71.0
							LYMPHOCYTES	19.5	%		19.0 - 52.0
							MONOCYTES	7.2	%		5.0 - 13.0
							EOSINOPHILS	5.9	%		1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	029	8	V1 (WEEK 0)	1	29JAN2010	10:00	BASOPHILS	0.5	%		< 1.0
			V3 (WEEK 12)	82	20APR2010	11:50	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.86	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	92.8	fL		79.4 - 94.8
							THROMBOCYTES	262	/nL		182 - 369
							LEUKOCYTES	6.6	/nL		4.0 - 10.0
							NEUTROPHILS	64.2	%		34.0 - 71.0
							LYMPHOCYTES	21.8	%		19.0 - 52.0
							MONOCYTES	6.6	%		5.0 - 13.0
							EOSINOPHILS	7.1	%	HIGH NCS	1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V4 (WEEK 24)	158	05JUL2010	11:10	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.84	fmol		1.59 - 2.00
							MCHC	18.8	mmol/L	LOW NCS	19.8 - 22.3
							MCV	97.9	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	220	/nL		182 - 369
							LEUKOCYTES	6.9	/nL		4.0 - 10.0
							NEUTROPHILS	68.7	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	029	8	V4 (WEEK 24)	158	05JUL2010	11:10	LYMPHOCYTES	19.4	%		19.0 - 52.0
							MONOCYTES	5.8	%		5.0 - 13.0
							EOSINOPHILS	5.5	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
			V5 (WEEK 36)	245	30SEP2010	11:25	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	19.7	mmol/L	LOW NCS	19.8 - 22.3
							MCV	91.6	fL		79.4 - 94.8
							THROMBOCYTES	270	/nL		182 - 369
							LEUKOCYTES	6.3	/nL		4.0 - 10.0
							NEUTROPHILS	66.7	%		34.0 - 71.0
							LYMPHOCYTES	19.5	%		19.0 - 52.0
							MONOCYTES	8.9	%		5.0 - 13.0
							EOSINOPHILS	4.6	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V6 (WEEK 52)	369	01FEB2011	11:45	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.84	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	90.8	fL		79.4 - 94.8

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	029	8	V6 (WEEK 52)	369	01FEB2011	11:45	THROMBOCYTES	266	/nL		182 - 369
							LEUKOCYTES	7.3	/nL		4.0 - 10.0
							NEUTROPHILS	67.7	%		34.0 - 71.0
							LYMPHOCYTES	19	%		19.0 - 52.0
							MONOCYTES	8	%		5.0 - 13.0
							EOSINOPHILS	4.8	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V7 (WEEK 56)	391	23FEB2011	11:05	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	89.4	fL		79.4 - 94.8
							THROMBOCYTES	262	/nL		182 - 369
							LEUKOCYTES	7.7	/nL		4.0 - 10.0
							NEUTROPHILS	75	%	HIGH CS	34.0 - 71.0
							LYMPHOCYTES	16.1	%	LOW NCS	19.0 - 52.0
							MONOCYTES	5.7	%		5.0 - 13.0
							EOSINOPHILS	2.7	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
	031	8	SCREENING	-14	06MAY2010	13:15	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9.3	mmol/L		8.5 - 10.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	031	8	SCREENING	-14	06MAY2010	13:15	HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.83	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	92.5	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	322	/nL		163 - 337
							LEUKOCYTES	8	/nL		4.2 - 9.1
							NEUTROPHILS	59.8	%		34.0 - 68.0
							LYMPHOCYTES	31.7	%		22.0 - 53.0
							MONOCYTES	6.1	%		5.0 - 12.0
							EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
							INR-VALUE	1.07			0.83 - 1.43
							aPTT	41.2	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	91	%		> 70
			V1 (WEEK 0)	1	20MAY2010	10:00	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.84	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	90.5	fL		79.0 - 92.2
							THROMBOCYTES	337	/nL		163 - 337
							LEUKOCYTES	8.4	/nL		4.2 - 9.1
							NEUTROPHILS	66.2	%		34.0 - 68.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	031	8	V1 (WEEK 0)	1	20MAY2010	10:00	LYMPHOCYTES	24	%		22.0 - 53.0
							MONOCYTES	8.1	%		5.0 - 12.0
							EOSINOPHILS	1.3	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V3 (WEEK 12)	90	17AUG2010	10:45	ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	8.8	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.77	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	90.9	fL		79.0 - 92.2
							THROMBOCYTES	338	/nL	HIGH NCS	163 - 337
							LEUKOCYTES	7.7	/nL		4.2 - 9.1
							NEUTROPHILS	68.7	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	22.1	%		22.0 - 53.0
							MONOCYTES	7.8	%		5.0 - 12.0
							EOSINOPHILS	1	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V4 (WEEK 24)	174	09NOV2010	11:35	ERYTHROCYTES	5.2	/pL		4.6 - 6.1
							HEMOGLOBIN	9.3	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.79	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	87.9	fL		79.0 - 92.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
Placebo	031	8	V4 (WEEK 24)	174	09NOV2010	11:35	THROMBOCYTES	389	/nL	HIGH	NCS	163 - 337
							LEUKOCYTES	8.6	/nL			4.2 - 9.1
							NEUTROPHILS	71.1	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	21.5	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	6.2	%			5.0 - 12.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.4	%			< 1.0
			V5 (WEEK 36)	251	25JAN2011	12:00	ERYTHROCYTES	5	/pL			4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.44	L/L			0.40 - 0.50
							MCH (HbE)	1.84	fmol			1.59 - 2.00
							MCHC	20.8	mmol/L			19.8 - 22.3
							MCV	88.3	fL			79.0 - 92.2
							THROMBOCYTES	335	/nL			163 - 337
							LEUKOCYTES	8.1	/nL			4.2 - 9.1
							NEUTROPHILS	72.6	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	21.1	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	5.3	%			5.0 - 12.0
							EOSINOPHILS	0.6	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.4	%			< 1.0
			V6 (WEEK 52)	363	17MAY2011	11:40	ERYTHROCYTES	5.2	/pL			4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.47	L/L			0.40 - 0.50

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	031	8	V6 (WEEK 52)	363	17MAY2011	11:40	MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	90	fL		79.0 - 92.2
							THROMBOCYTES	351	/nL	HIGH NCS	163 - 337
							LEUKOCYTES	8.9	/nL		4.2 - 9.1
							NEUTROPHILS	73.7	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	18.7	%	LOW NCS	22.0 - 53.0
							MONOCYTES	6.6	%		5.0 - 12.0
							EOSINOPHILS	0.8	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
		V7 (WEEK 56)		391	14JUN2011	10:14	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	19.7	mmol/L	LOW NCS	19.8 - 22.3
							MCV	92.5	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	313	/nL		163 - 337
							LEUKOCYTES	8	/nL		4.2 - 9.1
							NEUTROPHILS	70.5	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	21.3	%	LOW NCS	22.0 - 53.0
							MONOCYTES	6.8	%		5.0 - 12.0
							EOSINOPHILS	1.1	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	034	9	SCREENING	-22	24FEB2010	8:50	ERYTHROCYTES	5.2	/pL		3.9 - 5.2
							HEMOGLOBIN	9.9	mmol/L	HIGH NCS	6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	90.4	fL		79.4 - 94.8
							THROMBOCYTES	231	/nL		182 - 369
							LEUKOCYTES	6.6	/nL		4.0 - 10.0
							NEUTROPHILS	65.1	%		34.0 - 71.0
							LYMPHOCYTES	27.5	%		19.0 - 52.0
							MONOCYTES	5.7	%		5.0 - 13.0
							EOSINOPHILS	1.2	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
							INR-VALUE	1.08			0.83 - 1.43
							aPTT	43.7	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	88	%		> 70
			V1 (WEEK 0)	1	18MAR2010	8:50	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	9.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.89	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	91	fL		79.4 - 94.8
							THROMBOCYTES	225	/nL		182 - 369

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant	range
Placebo	034	9	V1 (WEEK 0)	1	18MAR2010	8:50	LEUKOCYTES	6.5	/nL		4.0 - 10.0
							NEUTROPHILS	68	%		34.0 - 71.0
							LYMPHOCYTES	25.9	%		19.0 - 52.0
							MONOCYTES	5.1	%		5.0 - 13.0
							EOSINOPHILS	0.5	%	LOW NCS	1.0 - 6.0
			V3 (WEEK 12)	83	08JUN2010	9:10	BASOPHILS	0.5	%		< 1.0
							ERYTHROCYTES	5.2	/pL		3.9 - 5.2
							HEMOGLOBIN	9.8	mmol/L	HIGH NCS	6.9 - 9.7
							HEMATOCRIT	0.51	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	19.3	mmol/L	LOW NCS	19.8 - 22.3
							MCV	97.1	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	93	/nL	LOW NCS	182 - 369
							LEUKOCYTES	6.7	/nL		4.0 - 10.0
							NEUTROPHILS	68.5	%		34.0 - 71.0
							LYMPHOCYTES	25.1	%		19.0 - 52.0
							MONOCYTES	4.7	%	LOW NCS	5.0 - 13.0
							EOSINOPHILS	1.2	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V4 (WEEK 24)	175	08SEP2010	8:40	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.3	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.89	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	034	9	V4 (WEEK 24)	175	08SEP2010	8:40	MCHC	20.4	mmol/L		19.8 - 22.3
							MCV	92.7	fL		79.4 - 94.8
							THROMBOCYTES	247	/nL		182 - 369
							LEUKOCYTES	10.4	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	76.4	%	HIGH NCS	34.0 - 71.0
							LYMPHOCYTES	16.5	%	LOW NCS	19.0 - 52.0
							MONOCYTES	5.5	%		5.0 - 13.0
			V5 (WEEK 36)	258	30NOV2010	8:00	EOSINOPHILS	1.3	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
							ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	10	mmol/L	HIGH NCS	6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	21.3	mmol/L		19.8 - 22.3
							MCV	91.8	fL		79.4 - 94.8
							THROMBOCYTES	221	/nL		182 - 369
							LEUKOCYTES	6	/nL		4.0 - 10.0
							NEUTROPHILS	59.6	%		34.0 - 71.0
							LYMPHOCYTES	29.8	%		19.0 - 52.0
							MONOCYTES	7.3	%		5.0 - 13.0
							EOSINOPHILS	2.8	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V6 (WEEK 52)	363	15MAR2011	8:25	ERYTHROCYTES	5	/pL		3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	034	9	V6 (WEEK 52)	363	15MAR2011	8:25	HEMOGLOBIN	9.6	mmol/L	HIGH	NCS	6.9 - 9.7
							HEMATOCRIT	0.46	L/L			0.35 - 0.45
							MCH (HbE)	1.93	fmol			1.59 - 2.00
							MCHC	20.8	mmol/L			19.8 - 22.3
							MCV	93	fL			79.4 - 94.8
							THROMBOCYTES	204	/nL			182 - 369
							LEUKOCYTES	6.7	/nL			4.0 - 10.0
							NEUTROPHILS	67.1	%			34.0 - 71.0
							LYMPHOCYTES	24.4	%			19.0 - 52.0
							MONOCYTES	6	%			5.0 - 13.0
							EOSINOPHILS	2.1	%			1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0
			V7 (WEEK 56)	399	20APR2011	8:25	ERYTHROCYTES	5.3	/pL	HIGH	NCS	3.9 - 5.2
							HEMOGLOBIN	10.4	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.5	L/L			0.35 - 0.45
							MCH (HbE)	1.95	fmol			1.59 - 2.00
							MCHC	20.7	mmol/L			19.8 - 22.3
							MCV	94.2	fL			79.4 - 94.8
							THROMBOCYTES	217	/nL			182 - 369
							LEUKOCYTES	7.1	/nL			4.0 - 10.0
							NEUTROPHILS	69.7	%			34.0 - 71.0
							LYMPHOCYTES	23.7	%			19.0 - 52.0
							MONOCYTES	4.8	%			LOW

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant	range
Placebo	034	9	V7 (WEEK 56)	399	20APR2011	8:25	EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
	041	12	SCREENING	-16	23SEP2009	10:30	ERYTHROCYTES	5	/pL		4.2 - 5.7
							HEMOGLOBIN	9.2	mmol/L		8.4 - 11.2
							HEMATOCRIT	0.49	L/L		0.39 - 0.55
							MCH (HbE)	1.85	fmol		1.74 - 1.99
							MCHC	19	mmol/L	LOW NCS	19.9 - 22.9
							MCV	97.2	fL	HIGH NCS	82.0 - 96.0
							THROMBOCYTES	209	/nL		150 - 400
							LEUKOCYTES	7.8	/nL		4.0 - 9.0
							NEUTROPHILS	74.4	%	HIGH NCS	50.0 - 70.0
							LYMPHOCYTES	19	%	LOW NCS	25.0 - 40.0
							MONOCYTES	5.6	%		2.0 - 14.0
							EOSINOPHILS	0.9	%		< 4.0
							BASOPHILS	0.1	%		< 1.0
							INR-VALUE	1.13			0.83 - 1.43
							aPTT	38.3	sec		26.0 - 40.0
							QUICK (VENOUS)	83	%		> 70
			V1 (WEEK 0)	1	09OCT2009	13:15	ERYTHROCYTES		/pL		4.2 - 5.7
							HEMOGLOBIN		mmol/L		8.4 - 11.2
							HEMATOCRIT		L/L		0.39 - 0.55
							MCH (HbE)		fmol		1.74 - 1.99

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	041	12	V1 (WEEK 0)	1	09OCT2009	13:15	MCHC		mmol/L		19.9 - 22.9
							MCV		fL		82.0 - 96.0
							THROMBOCYTES		/nL		150 - 400
							LEUKOCYTES		/nL		4.0 - 9.0
							NEUTROPHILS		%		50.0 - 70.0
			V3 (WEEK 12)	89	05JAN2010	9:40	ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	93.2	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	151	/nL	LOW NCS	163 - 337
							LEUKOCYTES	4.9	/nL		4.2 - 9.1
							NEUTROPHILS	73.4	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	20.7	%	LOW NCS	22.0 - 53.0
							MONOCYTES	5.1	%		5.0 - 12.0
							EOSINOPHILS	0.6	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V4 (WEEK 24)	167	24MAR2010	9:10	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	041	12	V4 (WEEK 24)	167	24MAR2010	9:10	MCV	95.1	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	165	/nL			163 - 337
							LEUKOCYTES	6.6	/nL			4.2 - 9.1
							NEUTROPHILS	63.7	%			34.0 - 68.0
							LYMPHOCYTES	30.2	%			22.0 - 53.0
							MONOCYTES	5	%			5.0 - 12.0
							EOSINOPHILS	0.9	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.2	%			< 1.0
			V5 (WEEK 36)	251	16JUN2010	9:15	ERYTHROCYTES	5	/pL			4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.49	L/L			0.40 - 0.50
							MCH (HbE)	1.92	fmol			1.59 - 2.00
							MCHC	19.5	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	98.4	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	166	/nL			163 - 337
							LEUKOCYTES	5.6	/nL			4.2 - 9.1
							NEUTROPHILS	70	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	24.6	%			22.0 - 53.0
							MONOCYTES	4.5	%	LOW	NCS	5.0 - 12.0
							EOSINOPHILS	0.7	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.2	%			< 1.0
			V6 (WEEK 52)	363	06OCT2010	8:30	ERYTHROCYTES	4.8	/pL			4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L			8.5 - 10.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	041	12	V6 (WEEK 52)	363	06OCT2010	8:30	HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.92	fmol		1.59 - 2.00
							MCHC	19.7	mmol/L	LOW NCS	19.8 - 22.3
							MCV	97.3	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	183	/nL		163 - 337
							LEUKOCYTES	5.8	/nL		4.2 - 9.1
							NEUTROPHILS	64.8	%		34.0 - 68.0
							LYMPHOCYTES	29	%		22.0 - 53.0
							MONOCYTES	5	%		5.0 - 12.0
							EOSINOPHILS	1	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V7 (WEEK 56)	392	04NOV2010	8:30	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	20.4	mmol/L		19.8 - 22.3
							MCV	94.7	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	193	/nL		163 - 337
							LEUKOCYTES	6.6	/nL		4.2 - 9.1
							NEUTROPHILS	69.9	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	24.3	%		22.0 - 53.0
							MONOCYTES	4.4	%	LOW NCS	5.0 - 12.0
							EOSINOPHILS	1.2	%		1.0 - 7.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant		Reference range
					Date	Time						
Placebo	041	12	V7 (WEEK 56)	392	04NOV2010	8:30	BASOPHILS	0.2	%			< 1.0
	044	12	SCREENING	-28	04NOV2009	9:25	ERYTHROCYTES	5.2	/pL			3.8 - 5.3
							HEMOGLOBIN	8.6	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.44	L/L			0.35 - 0.47
							MCH (HbE)	1.66	fmol	LOW	NCS	1.74 - 1.99
							MCHC	19.3	mmol/L	LOW	NCS	19.9 - 22.9
							MCV	86	fL			82.0 - 110
							THROMBOCYTES	132	/nL	LOW	NCS	150 - 400
							LEUKOCYTES	5	/nL			
							NEUTROPHILS	73.5	%	HIGH	NCS	50.0 - 70.0
							LYMPHOCYTES	20.3	%	LOW	NCS	25.0 - 40.0
							MONOCYTES	5	%			2.0 - 14.0
							EOSINOPHILS	1	%			< 4.0
							BASOPHILS	0.2	%			< 1.0
							INR-VALUE	1.03				0.83 - 1.43
							aPTT	38.8	sec			26.0 - 40.0
							QUICK (VENOUS)	95	%			> 70
			V1 (WEEK 0)	1	02DEC2009	9:40	ERYTHROCYTES	4.9	/pL			3.8 - 5.3
							HEMOGLOBIN	8.2	mmol/L			6.8 - 10.2
							HEMATOCRIT	0.41	L/L			0.35 - 0.47
							MCH (HbE)	1.67	fmol	LOW	NCS	1.74 - 1.99
							MCHC	19.8	mmol/L	LOW	NCS	19.9 - 22.9

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	044	12	V1 (WEEK 0)	1	02DEC2009	9:40	MCV	84.1	fL			82.0 - 96.0
			V3 (WEEK 12)	85	24FEB2010	9:20	THROMBOCYTES	115	/nL	LOW	NCS	150 - 400
							LEUKOCYTES	5	/nL			4.0 - 9.0
							NEUTROPHILS	67	%			50.0 - 70.0
							LYMPHOCYTES	26.4	%			25.0 - 40.0
							MONOCYTES	4.8	%			2.0 - 14.0
							EOSINOPHILS	1.4	%			< 4.0
							BASOPHILS	0.4	%			< 1.0
							ERYTHROCYTES	5.4	/pL		NCS	3.9 - 5.2
							HEMOGLOBIN	8.8	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.64	fmol			1.59 - 2.00
							MCHC	20.2	mmol/L			19.8 - 22.3
							MCV	81.7	fL			79.4 - 94.8
							THROMBOCYTES	120	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	6.7	/nL			4.0 - 10.0
							NEUTROPHILS	72.9	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	20.6	%			19.0 - 52.0
							MONOCYTES	6	%			5.0 - 13.0
							EOSINOPHILS	0.4	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.1	%			< 1.0
			V4 (WEEK 24)	176	26MAY2010	8:30	ERYTHROCYTES	5.6	/pL	HIGH	NCS	3.9 - 5.2
							HEMOGLOBIN	9.3	mmol/L			6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
Placebo	044	12	V4 (WEEK 24)	176	26MAY2010	8:30	HEMATOCRIT	0.47	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.67	fmol			1.59 - 2.00
							MCHC	19.9	mmol/L			19.8 - 22.3
							MCV	83.9	fL			79.4 - 94.8
							THROMBOCYTES	124	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	5.6	/nL			4.0 - 10.0
							NEUTROPHILS	64.1	%			34.0 - 71.0
							LYMPHOCYTES	29.5	%			19.0 - 52.0
							MONOCYTES	5.3	%			5.0 - 13.0
							EOSINOPHILS	0.9	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
			V5 (WEEK 36)	260	18AUG2010	8:30	ERYTHROCYTES	5.4	/pL	HIGH	NCS	3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.7	fmol			1.59 - 2.00
							MCHC	19.5	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	87.2	fL			79.4 - 94.8
							THROMBOCYTES	122	/nL	LOW	NCS	182 - 369
							LEUKOCYTES	6.5	/nL			4.0 - 10.0
							NEUTROPHILS	70.7	%			34.0 - 71.0
							LYMPHOCYTES	23.8	%			19.0 - 52.0
							MONOCYTES	4.4	%	LOW	NCS	5.0 - 13.0
							EOSINOPHILS	0.9	%	LOW	NCS	1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	044	12	V5 (WEEK 36)	260	18AUG2010	8:30	BASOPHILS	0.2	%		< 1.0
			V6 (WEEK 52)	365	01DEC2010	8:15	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	8.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.42	L/L		0.35 - 0.45
							MCH (HbE)	1.66	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	82.7	fL		79.4 - 94.8
							THROMBOCYTES	98	/nL	LOW NCS	182 - 369
							LEUKOCYTES	5	/nL		4.0 - 10.0
							NEUTROPHILS	69.1	%		34.0 - 71.0
							LYMPHOCYTES	23.9	%		19.0 - 52.0
							MONOCYTES	5.4	%		5.0 - 13.0
							EOSINOPHILS	1.2	%		1.0 - 6.0
			V7 (WEEK 56)	400	05JAN2011	9:10	BASOPHILS	0.4	%		< 1.0
							ERYTHROCYTES	5.2	/pL		3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.62	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	83.3	fL		79.4 - 94.8
							THROMBOCYTES	85	/nL	LOW NCS	182 - 369
							LEUKOCYTES	5	/nL		4.0 - 10.0
							NEUTROPHILS	69.4	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	044	12	V7 (WEEK 56)	400	05JAN2011	9:10	LYMPHOCYTES	22	%		19.0 - 52.0
							MONOCYTES	7.6	%		5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
	045	11	SCREENING	-14	07DEC2009	9:45	ERYTHROCYTES	4.8	/pL		4.2 - 5.7
							HEMOGLOBIN	9.1	mmol/L		8.4 - 11.2
							HEMATOCRIT	0.43	L/L		0.39 - 0.55
							MCH (HbE)	1.89	fmol		1.74 - 1.99
							MCHC	21.1	mmol/L		19.9 - 22.9
							MCV	89.5	fL		82.0 - 96.0
							THROMBOCYTES	159	/nL		150 - 400
							LEUKOCYTES	5.3	/nL		4.0 - 9.0
							NEUTROPHILS	44.4	%	LOW NCS	50.0 - 70.0
							LYMPHOCYTES	41.6	%	HIGH NCS	25.0 - 40.0
							MONOCYTES	10.3	%		2.0 - 14.0
							EOSINOPHILS	3	%		< 4.0
							BASOPHILS	0.7	%		< 1.0
							INR-VALUE	1.27			0.83 - 1.43
							aPTT	45.6	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	70	%	LOW NCS	> 70
			V1 (WEEK 0)	1	21DEC2009	9:15	ERYTHROCYTES	4.9	/pL		4.2 - 5.7
							HEMOGLOBIN	9.4	mmol/L		8.4 - 11.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	045	11	V1 (WEEK 0)	1	21DEC2009	9:15	HEMATOCRIT	0.45	L/L		0.39 - 0.55
							MCH (HbE)	1.91	fmol		1.74 - 1.99
							MCHC	21	mmol/L		19.9 - 22.9
							MCV	90.6	fL		82.0 - 96.0
							THROMBOCYTES	159	/nL		150 - 400
							LEUKOCYTES	6.4	/nL		4.0 - 9.0
							NEUTROPHILS	39.2	%	LOW NCS	50.0 - 70.0
							LYMPHOCYTES	46.9	%	HIGH NCS	25.0 - 40.0
							MONOCYTES	10.3	%		2.0 - 14.0
							EOSINOPHILS	2.8	%		< 4.0
							BASOPHILS	0.8	%		< 1.0
			V3 (WEEK 12)	85	15MAR2010	8:30	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	8.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.41	L/L		0.40 - 0.50
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	89.7	fL		79.0 - 92.2
							THROMBOCYTES	156	/nL	LOW NCS	163 - 337
							LEUKOCYTES	5.2	/nL		4.2 - 9.1
							NEUTROPHILS	45.2	%		34.0 - 68.0
							LYMPHOCYTES	41.8	%		22.0 - 53.0
							MONOCYTES	9.7	%		5.0 - 12.0
							EOSINOPHILS	2.1	%		1.0 - 7.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	045	11	V3 (WEEK 12)	85	15MAR2010	8:30	BASOPHILS	1.2	%	HIGH NCS	< 1.0
			V4 (WEEK 24)	169	07JUN2010	9:45	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	20.4	mmol/L		19.8 - 22.3
							MCV	93.1	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	165	/nL		163 - 337
							LEUKOCYTES	5.1	/nL		4.2 - 9.1
							NEUTROPHILS	47.3	%		34.0 - 68.0
							LYMPHOCYTES	39.8	%		22.0 - 53.0
							MONOCYTES	9.4	%		5.0 - 12.0
							EOSINOPHILS	2.5	%		1.0 - 7.0
			V5 (WEEK 36)	260	06SEP2010	9:15	BASOPHILS	1	%	HIGH NCS	< 1.0
							ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	90.6	fL		79.0 - 92.2
							THROMBOCYTES	152	/nL	LOW NCS	163 - 337
							LEUKOCYTES	6.2	/nL		4.2 - 9.1
							NEUTROPHILS	51	%		34.0 - 68.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	045	11	V5 (WEEK 36)	260	06SEP2010	9:15	LYMPHOCYTES	36.9	%		22.0 - 53.0
							MONOCYTES	9.6	%		5.0 - 12.0
							EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
			V6 (WEEK 52)	360	15DEC2010	8:30	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	90.1	fL		79.0 - 92.2
							THROMBOCYTES	177	/nL		163 - 337
							LEUKOCYTES	6.6	/nL		4.2 - 9.1
							NEUTROPHILS	44.2	%		34.0 - 68.0
							LYMPHOCYTES	42.1	%		22.0 - 53.0
							MONOCYTES	11.1	%		5.0 - 12.0
							EOSINOPHILS	1.8	%		1.0 - 7.0
							BASOPHILS	0.8	%		< 1.0
			V7 (WEEK 56)	393	17JAN2011	9:05	ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	21.1	mmol/L		19.8 - 22.3
							MCV	89.7	fL		79.0 - 92.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	045	11	V7 (WEEK 56)	393	17JAN2011	9:05	THROMBOCYTES	154	/nL	LOW	NCS	163 - 337
							LEUKOCYTES	6.1	/nL			4.2 - 9.1
							NEUTROPHILS	46.3	%			34.0 - 68.0
							LYMPHOCYTES	39.5	%			22.0 - 53.0
							MONOCYTES	11.2	%			5.0 - 12.0
							EOSINOPHILS	2.3	%			1.0 - 7.0
							BASOPHILS	0.7	%			< 1.0
	047	11	SCREENING	-21	12JUL2010	7:55	ERYTHROCYTES	4.6	/pL			4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.52	L/L			0.40 - 0.50
							MCH (HbE)	2.06	fmol			1.59 - 2.00
							MCHC	18.2	mmol/L			19.8 - 22.3
							MCV	113.6	fL			79.0 - 92.2
							THROMBOCYTES	202	/nL			163 - 337
							LEUKOCYTES	5.1	/nL			4.2 - 9.1
							NEUTROPHILS	60.1	%			34.0 - 68.0
							LYMPHOCYTES	25.6	%			22.0 - 53.0
							MONOCYTES	9.8	%			5.0 - 12.0
							EOSINOPHILS	3.7	%			1.0 - 7.0
							BASOPHILS	0.8	%			< 1.0
							INR-VALUE	1.04				0.83 - 1.43
							aPTT	34.3	sec			26.0 - 40.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	047	11	SCREENING V1 (WEEK 0)	-21 1	12JUL2010 02AUG2010	7:55 8:45	QUICK (VENOUS)	94	%		> 70
							ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	9.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.53	L/L	HIGH NCS	0.40 - 0.50
							MCH (HbE)	2.06	fmol	HIGH NCS	1.59 - 2.00
							MCHC	18.2	mmol/L	LOW NCS	19.8 - 22.3
							MCV	113.2	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	229	/nL		163 - 337
							LEUKOCYTES	5	/nL		4.2 - 9.1
							NEUTROPHILS	55.9	%		34.0 - 68.0
							LYMPHOCYTES	29.3	%		22.0 - 53.0
							MONOCYTES	10.6	%		5.0 - 12.0
							EOSINOPHILS	3.6	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
			V3 (WEEK 12)	80	20OCT2010	11:40	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	2.11	fmol	HIGH NCS	1.59 - 2.00
							MCHC	21.1	mmol/L		19.8 - 22.3
							MCV	99.8	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	229	/nL		163 - 337
							LEUKOCYTES	5.5	/nL		4.2 - 9.1
							NEUTROPHILS	53.5	%		34.0 - 68.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	047	11	V3 (WEEK 12)	80	20OCT2010	11:40	LYMPHOCYTES	25.9	%		22.0 - 53.0
			V4 (WEEK 24)	162	10JAN2011	9:30	MONOCYTES	15.7	%	HIGH NCS	5.0 - 12.0
							EOSINOPHILS	4	%		1.0 - 7.0
							BASOPHILS	0.9	%		< 1.0
							ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	2.06	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	99.6	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	241	/nL		163 - 337
							LEUKOCYTES	5.1	/nL		4.2 - 9.1
							NEUTROPHILS	55.6	%		34.0 - 68.0
							LYMPHOCYTES	26	%		22.0 - 53.0
							MONOCYTES	13.5	%	HIGH NCS	5.0 - 12.0
							EOSINOPHILS	3.9	%		1.0 - 7.0
							BASOPHILS	1	%	HIGH NCS	< 1.0
			V5 (WEEK 36)	254	12APR2011	9:15	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	2.1	fmol	HIGH NCS	1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	100	fL	HIGH NCS	79.0 - 92.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	047	11	V5 (WEEK 36)	254	12APR2011	9:15	THROMBOCYTES	256	/nL			163 - 337
							LEUKOCYTES	5.4	/nL			4.2 - 9.1
							NEUTROPHILS	58.2	%			34.0 - 68.0
							LYMPHOCYTES	26.8	%			22.0 - 53.0
							MONOCYTES	11.1	%			5.0 - 12.0
							EOSINOPHILS	3.3	%			1.0 - 7.0
							BASOPHILS	0.6	%			< 1.0
			V6 (WEEK 52)	360	27JUL2011	7:35	ERYTHROCYTES	4.7	/pL			4.6 - 6.1
							HEMOGLOBIN	9.7	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.49	L/L			0.40 - 0.50
							MCH (HbE)	2.07	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	19.8	mmol/L			19.8 - 22.3
							MCV	104.5	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	230	/nL			163 - 337
							LEUKOCYTES	5.5	/nL			4.2 - 9.1
							NEUTROPHILS	60.7	%			34.0 - 68.0
							LYMPHOCYTES	23.8	%			22.0 - 53.0
							MONOCYTES	11	%			5.0 - 12.0
							EOSINOPHILS	3.8	%			1.0 - 7.0
							BASOPHILS	0.7	%			< 1.0
			V7 (WEEK 56)	393	29AUG2011	7:45	ERYTHROCYTES	4.5	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.46	L/L			0.40 - 0.50

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	047	11	V7 (WEEK 56)	393	29AUG2011	7:45	MCH (HbE)	2.05	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.1	mmol/L		19.8 - 22.3
							MCV	101.8	fL		79.0 - 92.2
							THROMBOCYTES	195	/nL	HIGH NCS	163 - 337
							LEUKOCYTES	4.2	/nL		4.2 - 9.1
							NEUTROPHILS	54	%		34.0 - 68.0
							LYMPHOCYTES	28	%	HIGH NCS	22.0 - 53.0
							MONOCYTES	12.3	%		5.0 - 12.0
							EOSINOPHILS	5	%		1.0 - 7.0
							BASOPHILS	0.7	%		< 1.0
	049	21	SCREENING	-51	06SEP2010	10:45	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	8.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.42	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	91.5	fL		79.4 - 94.8
							THROMBOCYTES	277	/nL		182 - 369
							LEUKOCYTES	6.6	/nL		4.0 - 10.0
							NEUTROPHILS	63.5	%		34.0 - 71.0
							LYMPHOCYTES	27.3	%		19.0 - 52.0
							MONOCYTES	7.1	%		5.0 - 13.0
							EOSINOPHILS	1.5	%		1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	049	21	SCREENING	-51	06SEP2010	10:45	BASOPHILS	0.6	%		< 1.0
							INR-VALUE	0.93			0.83 - 1.43
							aPTT	37.6	sec		26.0 - 40.0
							QUICK (VENOUS)	113	%		> 70
			V1 (WEEK 0)	1	27OCT2010	8:55	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.42	L/L		0.35 - 0.45
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	90.9	fL		79.4 - 94.8
							THROMBOCYTES	252	/nL		182 - 369
							LEUKOCYTES	5.4	/nL		4.0 - 10.0
							NEUTROPHILS	63.2	%		34.0 - 71.0
							LYMPHOCYTES	24.1	%		19.0 - 52.0
							MONOCYTES	9.3	%		5.0 - 13.0
							EOSINOPHILS	2.8	%		1.0 - 6.0
			V3 (WEEK 12)	84	18JAN2011	10:30	BASOPHILS	0.6	%		< 1.0
							ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	8.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.81	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	89.5	fL		79.4 - 94.8

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	049	21	V3 (WEEK 12)	84	18JAN2011	10:30	THROMBOCYTES	283	/nL			182 - 369
							LEUKOCYTES	5.9	/nL			4.0 - 10.0
							NEUTROPHILS	65.7	%			34.0 - 71.0
							LYMPHOCYTES	23.7	%			19.0 - 52.0
							MONOCYTES	8.2	%			5.0 - 13.0
							EOSINOPHILS	1.9	%			1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0
			V4 (WEEK 24)	168	12APR2011	11:00	ERYTHROCYTES	4.8	/pL			3.9 - 5.2
							HEMOGLOBIN	8.8	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.42	L/L			0.35 - 0.45
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	20.9	mmol/L			19.8 - 22.3
							MCV	88.4	fL			79.4 - 94.8
							THROMBOCYTES	262	/nL			182 - 369
							LEUKOCYTES	6.8	/nL			4.0 - 10.0
							NEUTROPHILS	70.7	%			34.0 - 71.0
							LYMPHOCYTES	21.7	%			19.0 - 52.0
							MONOCYTES	6.4	%			5.0 - 13.0
							EOSINOPHILS	0.6	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.6	%			< 1.0
			V5 (WEEK 36)	252	05JUL2011	10:00	ERYTHROCYTES	4.3	/pL			3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.41	L/L			0.35 - 0.45

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant		Reference range
					Date	Time						
Placebo	049	21	V5 (WEEK 36)	252	05JUL2011	10:00	MCH (HbE)	1.81	fmol	LOW	NCS	1.59 - 2.00
							MCHC	19.2	mmol/L			19.8 - 22.3
							MCV	94.2	fL			79.4 - 94.8
							THROMBOCYTES	272	/nL			182 - 369
							LEUKOCYTES	9.6	/nL			4.0 - 10.0
							NEUTROPHILS	85.8	%			34.0 - 71.0
							LYMPHOCYTES	8.1	%			19.0 - 52.0
							MONOCYTES	5.3	%			5.0 - 13.0
							EOSINOPHILS	0.6	%			1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
	051	21	SCREENING	-52	06SEP2010	12:40	ERYTHROCYTES	4.8	/pL	HIGH	NCS	3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.44	L/L			0.35 - 0.45
							MCH (HbE)	1.88	fmol			1.59 - 2.00
							MCHC	20.7	mmol/L			19.8 - 22.3
							MCV	90.7	fL			79.4 - 94.8
							THROMBOCYTES	299	/nL			182 - 369
							LEUKOCYTES	10.1	/nL			4.0 - 10.0
							NEUTROPHILS	71	%			34.0 - 71.0
							LYMPHOCYTES	21.9	%			19.0 - 52.0
							MONOCYTES	5.8	%			5.0 - 13.0
							EOSINOPHILS	1	%			1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	051	21	SCREENING	-52	06SEP2010	12:40	BASOPHILS	0.3	%		< 1.0
							INR-VALUE	1.13			0.83 - 1.43
							aPTT	37.9	sec		26.0 - 40.0
							QUICK (VENOUS)	83	%		> 70
			V1 (WEEK 0)	1	28OCT2010	11:30	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	9.3	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	91.9	fL		79.4 - 94.8
							THROMBOCYTES	283	/nL		182 - 369
							LEUKOCYTES	10.3	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	66	%		34.0 - 71.0
							LYMPHOCYTES	24.9	%		19.0 - 52.0
							MONOCYTES	7	%		5.0 - 13.0
							EOSINOPHILS	1.9	%		1.0 - 6.0
			V3 (WEEK 12)	97	01FEB2011	11:30	BASOPHILS	0.2	%		< 1.0
							ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.84	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	91.2	fL		79.4 - 94.8

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	051	21	V3 (WEEK 12)	97	01FEB2011	11:30	THROMBOCYTES	293	/nL		182 - 369
							LEUKOCYTES	10.5	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	67.9	%		34.0 - 71.0
							LYMPHOCYTES	23.1	%		19.0 - 52.0
							MONOCYTES	7.6	%		5.0 - 13.0
							EOSINOPHILS	0.9	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V4 (WEEK 24)	167	12APR2011	13:30	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	91.3	fL		79.4 - 94.8
							THROMBOCYTES	313	/nL		182 - 369
							LEUKOCYTES	11.4	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	70	%		34.0 - 71.0
							LYMPHOCYTES	21.7	%		19.0 - 52.0
							MONOCYTES	6.4	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
			V5 (WEEK 36)	251	05JUL2011	13:42	ERYTHROCYTES	5.1	/pL		3.9 - 5.2
							HEMOGLOBIN	8.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.48	L/L	HIGH NCS	0.35 - 0.45

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	051	21	V5 (WEEK 36)	251	05JUL2011	13:42	MCH (HbE)	1.75	fmol	LOW	NCS	1.59 - 2.00
							MCHC	18.5	mmol/L			19.8 - 22.3
							MCV	94.3	fL			79.4 - 94.8
							THROMBOCYTES	301	/nL			182 - 369
							LEUKOCYTES	9.4	/nL			4.0 - 10.0
							NEUTROPHILS	59.9	%			34.0 - 71.0
							LYMPHOCYTES	29.8	%			19.0 - 52.0
							MONOCYTES	8.5	%			5.0 - 13.0
							EOSINOPHILS	1.6	%			1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
			V6 (WEEK 52)	363	25OCT2011	8:30	ERYTHROCYTES	5.1	/pL			3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.8	fmol			1.59 - 2.00
							MCHC	19.8	mmol/L			19.8 - 22.3
							MCV	91.2	fL			79.4 - 94.8
							THROMBOCYTES	300	/nL			182 - 369
							LEUKOCYTES	10.9	/nL			4.0 - 10.0
							NEUTROPHILS	70.5	%			34.0 - 71.0
							LYMPHOCYTES	21.3	%			19.0 - 52.0
							MONOCYTES	6.2	%			5.0 - 13.0
							EOSINOPHILS	1.8	%			1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	051	21	V7 (WEEK 56)	391	22NOV2011	8:30	ERYTHROCYTES	5.2	/pL		3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.51	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.78	fmol		1.59 - 2.00
							MCHC	18.2	mmol/L	LOW NCS	19.8 - 22.3
							MCV	97.5	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	378	/nL	HIGH NCS	182 - 369
							LEUKOCYTES	12.1	/nL	HIGH NCS	4.0 - 10.0
							NEUTROPHILS	65.4	%		34.0 - 71.0
							LYMPHOCYTES	26.2	%		19.0 - 52.0
							MONOCYTES	6.4	%		5.0 - 13.0
							EOSINOPHILS	1.6	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
	056	5	SCREENING	-21	31MAR2010	10:00	ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	8.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	21.1	mmol/L		19.8 - 22.3
							MCV	91.7	fL		79.4 - 94.8
							THROMBOCYTES	219	/nL		182 - 369
							LEUKOCYTES	5.7	/nL		4.0 - 10.0
							NEUTROPHILS	56.8	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	056	5	SCREENING	-21	31MAR2010	10:00	LYMPHOCYTES	25.2	%		19.0 - 52.0
							MONOCYTES	13.1	%	HIGH NCS	5.0 - 13.0
							EOSINOPHILS	4.2	%		1.0 - 6.0
							BASOPHILS	0.7	%		< 1.0
							INR-VALUE	1.07			0.83 - 1.43
							aPTT	34.4	sec		26.0 - 40.0
							QUICK (VENOUS)	89	%		> 70
			V1 (WEEK 0)	1	21APR2010	9:15	ERYTHROCYTES	4.2	/pL		3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	93.8	fL		79.4 - 94.8
							THROMBOCYTES	201	/nL		182 - 369
							LEUKOCYTES	4.2	/nL		4.0 - 10.0
							NEUTROPHILS	51.2	%		34.0 - 71.0
							LYMPHOCYTES	29.3	%		19.0 - 52.0
							MONOCYTES	13.7	%	HIGH NCS	5.0 - 13.0
							EOSINOPHILS	4.8	%		1.0 - 6.0
							BASOPHILS	1	%	HIGH NCS	< 1.0
			V3 (WEEK 12)	84	13JUL2010	11:15	ERYTHROCYTES	3.6	/pL	LOW NCS	3.9 - 5.2
							HEMOGLOBIN	6.9	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.37	L/L		0.35 - 0.45

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	056	5	V3 (WEEK 12)	84	13JUL2010	11:15	MCH (HbE)	1.95	fmol			1.59 - 2.00
							MCHC	18.8	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	104.2	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	352	/nL			182 - 369
							LEUKOCYTES	7.6	/nL			4.0 - 10.0
							NEUTROPHILS	62.3	%			34.0 - 71.0
							LYMPHOCYTES	25.6	%			19.0 - 52.0
							MONOCYTES	9.5	%			5.0 - 13.0
							EOSINOPHILS	2.2	%			1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0
			V4 (WEEK 24)	168	05OCT2010	9:15	ERYTHROCYTES	4.4	/pL			3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.41	L/L			0.35 - 0.45
							MCH (HbE)	1.88	fmol			1.59 - 2.00
							MCHC	20.3	mmol/L			19.8 - 22.3
							MCV	92.9	fL			79.4 - 94.8
							THROMBOCYTES	199	/nL			182 - 369
							LEUKOCYTES	5.7	/nL			4.0 - 10.0
							NEUTROPHILS	53.9	%			34.0 - 71.0
							LYMPHOCYTES	28.1	%			19.0 - 52.0
							MONOCYTES	14.9	%			5.0 - 13.0
							EOSINOPHILS	2.7	%	HIGH	NCS	1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	056	5	V5 (WEEK 36)	259	04JAN2011	8:50	ERYTHROCYTES	4.3	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.97	fmol		1.59 - 2.00
							MCHC	21	mmol/L		19.8 - 22.3
							MCV	94	fL		79.4 - 94.8
							THROMBOCYTES	224	/nL		182 - 369
							LEUKOCYTES	6	/nL		4.0 - 10.0
							NEUTROPHILS	61.2	%		34.0 - 71.0
							LYMPHOCYTES	20.6	%		19.0 - 52.0
			V6 (WEEK 52)	364	19APR2011	8:05	MONOCYTES	14.9	%	HIGH NCS	5.0 - 13.0
							EOSINOPHILS	2.8	%		1.0 - 6.0
							BASOPHILS	0.5	%		< 1.0
							ERYTHROCYTES	4.3	/pL		3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.4	L/L		0.35 - 0.45
							MCH (HbE)	1.93	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	94.6	fL		79.4 - 94.8
							THROMBOCYTES	184	/nL		182 - 369
							LEUKOCYTES	5.5	/nL		4.0 - 10.0
							NEUTROPHILS	61.3	%		34.0 - 71.0
							LYMPHOCYTES	23.7	%		19.0 - 52.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	056	5	V6 (WEEK 52)	364	19APR2011	8:05	MONOCYTES	11.9	%		5.0 - 13.0
							EOSINOPHILS	2.9	%		1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
	058	1	SCREENING	-21	06DEC2010	10:00	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	8.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.43	L/L		0.40 - 0.50
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	91	fL		79.0 - 92.2
							THROMBOCYTES	289	/nL		163 - 337
							LEUKOCYTES	6.8	/nL		4.2 - 9.1
							NEUTROPHILS	61.2	%		34.0 - 68.0
							LYMPHOCYTES	25.8	%		22.0 - 53.0
							MONOCYTES	7.6	%		5.0 - 12.0
							EOSINOPHILS	5	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	1.08			0.83 - 1.43
							aPTT	35.9	sec		26.0 - 40.0
							QUICK (VENOUS)	88	%		> 70
							ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
			V1 (WEEK 0)	1	27DEC2010	11:15					

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	058	1	V1 (WEEK 0)	1	27DEC2010	11:15	MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	91.9	fL		79.0 - 92.2
							THROMBOCYTES	372	/nL	HIGH NCS	163 - 337
							LEUKOCYTES	6.8	/nL		4.2 - 9.1
							NEUTROPHILS	59.7	%		34.0 - 68.0
							LYMPHOCYTES	21.1	%	LOW NCS	22.0 - 53.0
							MONOCYTES	12.6	%	HIGH NCS	5.0 - 12.0
							EOSINOPHILS	6	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
			V3 (WEEK 12)	93	29MAR2011	11:10	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.3	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.94	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	92.9	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	331	/nL		163 - 337
							LEUKOCYTES	7	/nL		4.2 - 9.1
							NEUTROPHILS	62.1	%		34.0 - 68.0
							LYMPHOCYTES	21.2	%	LOW NCS	22.0 - 53.0
							MONOCYTES	9.2	%		5.0 - 12.0
							EOSINOPHILS	6.9	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	058	1	V4 (WEEK 24)	166	10JUN2011	10:15	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.5	L/L		0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	17.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	108.7	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	306	/nL		163 - 337
							LEUKOCYTES	5.7	/nL		4.2 - 9.1
							NEUTROPHILS	69	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	21.4	%	LOW NCS	22.0 - 53.0
			V5 (WEEK 36)	260	12SEP2011	10:55	MONOCYTES	6.9	%		5.0 - 12.0
							EOSINOPHILS	2.5	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
							ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.94	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	96	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	297	/nL		163 - 337
							LEUKOCYTES	6.5	/nL		4.2 - 9.1
							NEUTROPHILS	69.2	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	21.1	%	LOW NCS	22.0 - 53.0

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant	range
Placebo	058	1	V5 (WEEK 36)	260	12SEP2011	10:55	MONOCYTES	6.8	%		5.0 - 12.0
							EOSINOPHILS	2.6	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
			V6 (WEEK 52)	345	06DEC2011	9:15	ERYTHROCYTES	4.5	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.42	L/L		0.40 - 0.50
							MCH (HbE)	2	fmol		1.59 - 2.00
							MCHC	21.5	mmol/L		19.8 - 22.3
							MCV	93.1	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	318	/nL		163 - 337
							LEUKOCYTES	6.6	/nL		4.2 - 9.1
							NEUTROPHILS	68.1	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	17.8	%	LOW NCS	22.0 - 53.0
							MONOCYTES	8.5	%		5.0 - 12.0
							EOSINOPHILS	5	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
			V7 (WEEK 56)	380	10JAN2012	10:25	ERYTHROCYTES	4.5	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.42	L/L		0.40 - 0.50
							MCH (HbE)	1.94	fmol		1.59 - 2.00
							MCHC	20.9	mmol/L		19.8 - 22.3
							MCV	92.7	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	341	/nL	HIGH NCS	163 - 337

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	058	1	V7 (WEEK 56)	380	10JAN2012	10:25	LEUKOCYTES	7.6	/nL		4.2 - 9.1
							NEUTROPHILS	69.1	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	15.4	%	LOW NCS	22.0 - 53.0
							MONOCYTES	8.6	%		5.0 - 12.0
							EOSINOPHILS	6.4	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
	059	1	SCREENING	-2	27DEC2010	13:00	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	20.4	mmol/L		19.8 - 22.3
							MCV	93.3	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	177	/nL		163 - 337
							LEUKOCYTES	5.6	/nL		4.2 - 9.1
							NEUTROPHILS	51.5	%		34.0 - 68.0
							LYMPHOCYTES	33.9	%		22.0 - 53.0
							MONOCYTES	9.3	%		5.0 - 12.0
							EOSINOPHILS	4.8	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
							INR-VALUE	1.05			0.83 - 1.43
							aPTT	39.7	sec		26.0 - 40.0
							QUICK (VENOUS)	93	%		> 70

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	059	1	V1 (WEEK 0)	1	29DEC2010	10:05	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.48	L/L		0.40 - 0.50
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	94.7	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	163	/nL		163 - 337
							LEUKOCYTES	5	/nL		4.2 - 9.1
							NEUTROPHILS	46.3	%		34.0 - 68.0
							LYMPHOCYTES	38.3	%		22.0 - 53.0
							MONOCYTES	8.3	%		5.0 - 12.0
							EOSINOPHILS	6.5	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
			V3 (WEEK 12)	93	31MAR2011	9:40	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.49	L/L		0.40 - 0.50
							MCH (HbE)	1.95	fmol		1.59 - 2.00
							MCHC	20.1	mmol/L		19.8 - 22.3
							MCV	96.9	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	186	/nL		163 - 337
							LEUKOCYTES	6	/nL		4.2 - 9.1
							NEUTROPHILS	52.9	%		34.0 - 68.0
							LYMPHOCYTES	33.1	%		22.0 - 53.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	059	1	V3 (WEEK 12)	93	31MAR2011	9:40	MONOCYTES	8.3	%		5.0 - 12.0
			V4 (WEEK 24)	161	07JUN2011	9:00	EOSINOPHILS	5.2	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
							ERYTHROCYTES	5.2	/pL		4.6 - 6.1
							HEMOGLOBIN	9.8	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.53	L/L	HIGH NCS	0.40 - 0.50
							MCH (HbE)	1.9	fmol		1.59 - 2.00
							MCHC	18.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	101.9	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	188	/nL		163 - 337
							LEUKOCYTES	5	/nL		4.2 - 9.1
							NEUTROPHILS	45.4	%		34.0 - 68.0
							LYMPHOCYTES	40.1	%		22.0 - 53.0
							MONOCYTES	8.5	%		5.0 - 12.0
							EOSINOPHILS	5.4	%		1.0 - 7.0
							BASOPHILS	0.6	%		< 1.0
			V5 (WEEK 36)	254	08SEP2011	10:15	ERYTHROCYTES	5	/pL		4.6 - 6.1
							HEMOGLOBIN	9.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.49	L/L		0.40 - 0.50
							MCH (HbE)	1.94	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	96.8	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	199	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	059	1	V5 (WEEK 36)	254	08SEP2011	10:15	LEUKOCYTES	5.6	/nL	HIGH NCS	4.2 - 9.1
							NEUTROPHILS	49.2	%		34.0 - 68.0
							LYMPHOCYTES	34.5	%		22.0 - 53.0
							MONOCYTES	10.2	%		5.0 - 12.0
							EOSINOPHILS	5.7	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V6 (WEEK 52)	345	08DEC2011	10:00	ERYTHROCYTES	5.1	/pL		4.6 - 6.1
							HEMOGLOBIN	9.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	1.92	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	93.5	fL		79.0 - 92.2
							THROMBOCYTES	190	/nL		163 - 337
							LEUKOCYTES	6.5	/nL		4.2 - 9.1
							NEUTROPHILS	51.5	%		34.0 - 68.0
							LYMPHOCYTES	31.1	%		22.0 - 53.0
							MONOCYTES	10.1	%		5.0 - 12.0
							EOSINOPHILS	6.5	%		1.0 - 7.0
			V7 (WEEK 56)	380	12JAN2012	11:00	BASOPHILS	0.8	%		< 1.0
							ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	9.2	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.95	fmol		1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	059	1	V7 (WEEK 56)	380	12JAN2012	11:00	MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	93.4	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	164	/nL		163 - 337
							LEUKOCYTES	5.4	/nL		4.2 - 9.1
							NEUTROPHILS	47.7	%		34.0 - 68.0
							LYMPHOCYTES	34.2	%		22.0 - 53.0
							MONOCYTES	11.3	%		5.0 - 12.0
							EOSINOPHILS	5.9	%		1.0 - 7.0
							BASOPHILS	0.9	%		< 1.0
	065	16	SCREENING	-20	10AUG2010	11:20	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.5	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.48	L/L		0.40 - 0.50
							MCH (HbE)	2.06	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.1	mmol/L		19.8 - 22.3
							MCV	102.8	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	229	/nL		163 - 337
							LEUKOCYTES	5.7	/nL		4.2 - 9.1
							NEUTROPHILS	71.8	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	20.4	%	LOW NCS	22.0 - 53.0
							MONOCYTES	6.6	%		5.0 - 12.0
							EOSINOPHILS	0.9	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	065	16	SCREENING	-20	10AUG2010	11:20	INR-VALUE	1.06			0.83 - 1.43
							aPTT	39.9	sec		26.0 - 40.0
							QUICK (VENOUS)	92	%		> 70
			V1 (WEEK 0)	1	30AUG2010	9:05	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	10	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.47	L/L		0.40 - 0.50
							MCH (HbE)	2.08	fmol	HIGH NCS	1.59 - 2.00
							MCHC	21.1	mmol/L		19.8 - 22.3
							MCV	98.8	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	222	/nL		163 - 337
							LEUKOCYTES	12.1	/nL	HIGH NCS	4.2 - 9.1
							NEUTROPHILS	85.4	%	HIGH NCS	34.0 - 68.0
							LYMPHOCYTES	10.3	%	LOW NCS	22.0 - 53.0
							MONOCYTES	4	%	LOW NCS	5.0 - 12.0
							EOSINOPHILS	0.1	%	LOW NCS	1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V3 (WEEK 12)	85	22NOV2010	10:50	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	9.4	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	2.05	fmol	HIGH NCS	1.59 - 2.00
							MCHC	20.9	mmol/L		19.8 - 22.3
							MCV	97.8	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	264	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	065	16	V3 (WEEK 12)	85	22NOV2010	10:50	LEUKOCYTES	6.1	/nL			4.2 - 9.1
							NEUTROPHILS	73.7	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	15.8	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	9.2	%			5.0 - 12.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.5	%			< 1.0
			V4 (WEEK 24)	141	17JAN2011	11:50	ERYTHROCYTES	4.2	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	9	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.44	L/L			0.40 - 0.50
							MCH (HbE)	2.12	fmol	HIGH	NCS	1.59 - 2.00
							MCHC	20.6	mmol/L			19.8 - 22.3
							MCV	102.6	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	192	/nL			163 - 337
							LEUKOCYTES	6.7	/nL			4.2 - 9.1
							NEUTROPHILS	78.2	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	10.7	%	LOW	NCS	22.0 - 53.0
							MONOCYTES	10.7	%			5.0 - 12.0
							EOSINOPHILS	0.3	%	LOW	NCS	1.0 - 7.0
							BASOPHILS	0.1	%			< 1.0
	068	16	SCREENING	-27	26OCT2010	8:55	ERYTHROCYTES	4.5	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	8.4	mmol/L	LOW	NCS	8.5 - 10.9
							HEMATOCRIT	0.41	L/L			0.40 - 0.50

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	068	16	SCREENING	-27	26OCT2010	8:55	MCH (HbE)	1.86	fmol			1.59 - 2.00
							MCHC	20.6	mmol/L			19.8 - 22.3
							MCV	90.1	fL			79.0 - 92.2
							THROMBOCYTES	231	/nL			163 - 337
							LEUKOCYTES	3.5	/nL	LOW	NCS	4.2 - 9.1
							NEUTROPHILS	55.6	%			34.0 - 68.0
							LYMPHOCYTES	29.6	%			22.0 - 53.0
							MONOCYTES	9.1	%			5.0 - 12.0
							EOSINOPHILS	4.8	%			1.0 - 7.0
							BASOPHILS	0.9	%			< 1.0
							INR-VALUE	1.2				0.83 - 1.43
							aPTT	42.4	sec	HIGH	NCS	26.0 - 40.0
							QUICK (VENOUS)	76	%			> 70
			V1 (WEEK 0)	1	22NOV2010	10:10	ERYTHROCYTES	4.7	/pL			4.6 - 6.1
							HEMOGLOBIN	8.6	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.42	L/L			0.40 - 0.50
							MCH (HbE)	1.84	fmol			1.59 - 2.00
							MCHC	20.5	mmol/L			19.8 - 22.3
							MCV	89.7	fL			79.0 - 92.2
							THROMBOCYTES	237	/nL			163 - 337
							LEUKOCYTES	4.1	/nL	LOW	NCS	4.2 - 9.1
							NEUTROPHILS	61.7	%			34.0 - 68.0
							LYMPHOCYTES	25.2	%			22.0 - 53.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	068	16	V1 (WEEK 0)	1	22NOV2010	10:10	MONOCYTES	8.4	%		5.0 - 12.0
							EOSINOPHILS	4	%		1.0 - 7.0
							BASOPHILS	0.7	%		< 1.0
			V3 (WEEK 12)	81	14FEB2011	9:00	ERYTHROCYTES	4.5	/pL	LOW NCS	4.6 - 6.1
							HEMOGLOBIN	8.4	mmol/L	LOW NCS	8.5 - 10.9
							HEMATOCRIT	0.4	L/L		0.40 - 0.50
							MCH (HbE)	1.86	fmol		1.59 - 2.00
							MCHC	20.9	mmol/L		19.8 - 22.3
							MCV	88.8	fL		79.0 - 92.2
							THROMBOCYTES	207	/nL		163 - 337
							LEUKOCYTES	3.1	/nL	LOW NCS	4.2 - 9.1
							NEUTROPHILS	56.7	%		34.0 - 68.0
							LYMPHOCYTES	30.7	%		22.0 - 53.0
							MONOCYTES	8.4	%		5.0 - 12.0
							EOSINOPHILS	3.2	%		1.0 - 7.0
							BASOPHILS	1	%	HIGH NCS	< 1.0
			V4 (WEEK 24)	163	03MAY2011	10:30	ERYTHROCYTES	4.7	/pL		4.6 - 6.1
							HEMOGLOBIN	8.4	mmol/L	LOW NCS	8.5 - 10.9
							HEMATOCRIT	0.42	L/L		0.40 - 0.50
							MCH (HbE)	1.8	fmol		1.59 - 2.00
							MCHC	20.3	mmol/L		19.8 - 22.3
							MCV	88.9	fL		79.0 - 92.2
							THROMBOCYTES	217	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
Placebo	068	16	V4 (WEEK 24)	163	03MAY2011	10:30	LEUKOCYTES	3.4	/nL	LOW	NCS	4.2 - 9.1
							NEUTROPHILS	58	%			34.0 - 68.0
							LYMPHOCYTES	27.6	%			22.0 - 53.0
							MONOCYTES	9.4	%			5.0 - 12.0
							EOSINOPHILS	4.4	%			1.0 - 7.0
			V5 (WEEK 36)	262	10AUG2011	9:10	BASOPHILS	0.6	%			< 1.0
							ERYTHROCYTES	4.9	/pL			4.6 - 6.1
							HEMOGLOBIN	8.8	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.45	L/L			0.40 - 0.50
							MCH (HbE)	1.81	fmol			1.59 - 2.00
							MCHC	19.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	91.6	fL			79.0 - 92.2
							THROMBOCYTES	181	/nL			163 - 337
							LEUKOCYTES	4.3	/nL			4.2 - 9.1
							NEUTROPHILS	57.2	%			34.0 - 68.0
							LYMPHOCYTES	29	%			22.0 - 53.0
							MONOCYTES	8.9	%			5.0 - 12.0
							EOSINOPHILS	4.2	%			1.0 - 7.0
							BASOPHILS	0.7	%			< 1.0
			V6 (WEEK 52)	372	28NOV2011	10:30	ERYTHROCYTES	4.4	/pL	LOW	NCS	4.6 - 6.1
							HEMOGLOBIN	8.1	mmol/L	LOW	NCS	8.5 - 10.9
							HEMATOCRIT	0.39	L/L	LOW	NCS	0.40 - 0.50
							MCH (HbE)	1.82	fmol			1.59 - 2.00

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	068	16	V6 (WEEK 52)	372	28NOV2011	10:30	MCHC	21	mmol/L		19.8 - 22.3
							MCV	87.1	fL		79.0 - 92.2
							THROMBOCYTES	272	/nL		163 - 337
							LEUKOCYTES	3.1	/nL	LOW NCS	4.2 - 9.1
							NEUTROPHILS	62.8	%		34.0 - 68.0
							LYMPHOCYTES	25.8	%		22.0 - 53.0
							MONOCYTES	8.8	%		5.0 - 12.0
							EOSINOPHILS	2.3	%		1.0 - 7.0
							BASOPHILS	0.3	%		< 1.0
			V7 (WEEK 56)	414	09JAN2012	11:45	ERYTHROCYTES	4.6	/pL		4.6 - 6.1
							HEMOGLOBIN	8.6	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.4	L/L		0.40 - 0.50
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	21.5	mmol/L		19.8 - 22.3
							MCV	86.9	fL		79.0 - 92.2
							THROMBOCYTES	234	/nL		163 - 337
							LEUKOCYTES	4.1	/nL	LOW NCS	4.2 - 9.1
							NEUTROPHILS	60.8	%		34.0 - 68.0
							LYMPHOCYTES	24.5	%		22.0 - 53.0
							MONOCYTES	9.8	%		5.0 - 12.0
							EOSINOPHILS	4.2	%		1.0 - 7.0
							BASOPHILS	0.7	%		< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	069	23	SCREENING	-13	24NOV2010	9:42	ERYTHROCYTES	5.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.52	L/L	HIGH NCS	0.40 - 0.50
							MCH (HbE)	1.71	fmol		1.59 - 2.00
							MCHC	19	mmol/L	LOW NCS	19.8 - 22.3
							MCV	89.9	fL		79.0 - 92.2
							THROMBOCYTES	221	/nL		163 - 337
							LEUKOCYTES	5.3	/nL		4.2 - 9.1
							NEUTROPHILS	61	%		34.0 - 68.0
							LYMPHOCYTES	30	%		22.0 - 53.0
							MONOCYTES	6.4	%		5.0 - 12.0
							EOSINOPHILS	2.2	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
							INR-VALUE	1.19			0.83 - 1.43
							aPTT	49	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	77	%		> 70
			V1 (WEEK 0)	1	07DEC2010	12:30	ERYTHROCYTES	5.7	/pL		4.6 - 6.1
							HEMOGLOBIN	10	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.48	L/L		0.40 - 0.50
							MCH (HbE)	1.77	fmol		1.59 - 2.00
							MCHC	20.8	mmol/L		19.8 - 22.3
							MCV	85.2	fL		79.0 - 92.2
							THROMBOCYTES	172	/nL		163 - 337

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High	signi- ficant	
Placebo	069	23	V1 (WEEK 0)	1	07DEC2010	12:30	LEUKOCYTES	1.7	/nL	LOW	NCS	4.2 - 9.1
							NEUTROPHILS		%			34 - 68
			V3 (WEEK 12)	93	09MAR2011	12:20	ERYTHROCYTES	5.9	/pL			4.6 - 6.1
							HEMOGLOBIN	10.4	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.54	L/L	HIGH	NCS	0.40 - 0.50
							MCH (HbE)	1.76	fmol			1.59 - 2.00
							MCHC	19.2	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	91.7	fL			79.0 - 92.2
							THROMBOCYTES	291	/nL			163 - 337
							LEUKOCYTES	7.4	/nL			4.2 - 9.1
							NEUTROPHILS	65.4	%			34.0 - 68.0
							LYMPHOCYTES	24.9	%			22.0 - 53.0
							MONOCYTES	7.4	%			5.0 - 12.0
							EOSINOPHILS	1.9	%			1.0 - 7.0
							BASOPHILS	0.4	%			< 1.0
			V4 (WEEK 24)	164	19MAY2011	9:30	ERYTHROCYTES	5.4	/pL			4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.45	L/L			0.40 - 0.50
							MCH (HbE)	1.69	fmol			1.59 - 2.00
							MCHC	20	mmol/L			19.8 - 22.3
							MCV	84.5	fL			79.0 - 92.2
							THROMBOCYTES	356	/nL	HIGH	NCS	163 - 337
							LEUKOCYTES	6.6	/nL			4.2 - 9.1

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	069	23	V4 (WEEK 24)	164	19MAY2011	9:30	NEUTROPHILS	69.5	%	HIGH	NCS	34.0 - 68.0
							LYMPHOCYTES	23.5	%			22.0 - 53.0
							MONOCYTES	4.9	%	LOW	NCS	5.0 - 12.0
							EOSINOPHILS	1.8	%			1.0 - 7.0
							BASOPHILS	0.3	%			< 1.0
			V5 (WEEK 36)	261	24AUG2011	11:00	ERYTHROCYTES	6	/pL			4.6 - 6.1
							HEMOGLOBIN	10	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.54	L/L	HIGH	NCS	0.40 - 0.50
							MCH (HbE)	1.67	fmol			1.59 - 2.00
							MCHC	18.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	90	fL			79.0 - 92.2
							THROMBOCYTES	201	/nL			163 - 337
							LEUKOCYTES	4.6	/nL			4.2 - 9.1
							NEUTROPHILS	56.7	%			34.0 - 68.0
							LYMPHOCYTES	32.8	%			22.0 - 53.0
							MONOCYTES	8.1	%			5.0 - 12.0
							EOSINOPHILS	2.2	%			1.0 - 7.0
							BASOPHILS	0.2	%			< 1.0
			V6 (WEEK 52)	373	14DEC2011	9:00	ERYTHROCYTES	5.9	/pL			4.6 - 6.1
							HEMOGLOBIN	9.9	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.47	L/L			0.40 - 0.50
							MCH (HbE)	1.67	fmol			1.59 - 2.00
							MCHC	21.1	mmol/L			19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	069	23	V6 (WEEK 52)	373	14DEC2011	9:00	MCV	79.3	fL		79.0 - 92.2
							THROMBOCYTES	233	/nL		163 - 337
							LEUKOCYTES	5.7	/nL		4.2 - 9.1
							NEUTROPHILS	58.5	%		34.0 - 68.0
							LYMPHOCYTES	30.2	%		22.0 - 53.0
							MONOCYTES	8.8	%		5.0 - 12.0
							EOSINOPHILS	2.1	%		1.0 - 7.0
							BASOPHILS	0.4	%		< 1.0
			V7 (WEEK 56)	401	11JAN2012	9:00	ERYTHROCYTES	5.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.9	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.71	fmol		1.59 - 2.00
							MCHC	21.6	mmol/L		19.8 - 22.3
							MCV	79.3	fL		79.0 - 92.2
	072	18	SCREENING	-20	01DEC2010	11:10	THROMBOCYTES	231	/nL		163 - 337
							LEUKOCYTES	5.9	/nL		4.2 - 9.1
							NEUTROPHILS	57.9	%		34.0 - 68.0
							LYMPHOCYTES	29.8	%		22.0 - 53.0
							MONOCYTES	9.9	%		5.0 - 12.0
							EOSINOPHILS	1.9	%		1.0 - 7.0
							BASOPHILS	0.5	%		< 1.0
							ERYTHROCYTES	5.3	/pL	HIGH NCS	3.9 - 5.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	072	18	SCREENING	-20	01DEC2010	11:10	HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.71	fmol		1.59 - 2.00
							MCHC	19.2	mmol/L	LOW NCS	19.8 - 22.3
							MCV	89.1	fL		79.4 - 94.8
							THROMBOCYTES	193	/nL		182 - 369
							LEUKOCYTES	3.2	/nL	LOW NCS	4.0 - 10.0
							NEUTROPHILS	54.9	%		34.0 - 71.0
							LYMPHOCYTES	35.8	%		19.0 - 52.0
							MONOCYTES	6.2	%		5.0 - 13.0
							EOSINOPHILS	1.9	%		1.0 - 6.0
							BASOPHILS	1.2	%	HIGH NCS	< 1.0
							INR-VALUE	1.15			0.83 - 1.43
							aPTT	46.4	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	81	%		> 70
			V1 (WEEK 0)	1	21DEC2010	12:15	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.69	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	86.6	fL		79.4 - 94.8
							THROMBOCYTES	261	/nL		182 - 369
							LEUKOCYTES	7.4	/nL		4.0 - 10.0

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	072	18	V1 (WEEK 0)	1	21DEC2010	12:15	NEUTROPHILS	79.9	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	14.7	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	4.7	%	LOW	NCS	5.0 - 13.0
							EOSINOPHILS	0.4	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
			V3 (WEEK 12)	85	15MAR2011	9:55	ERYTHROCYTES	4.7	/pL		NCS	3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L		NCS	6.9 - 9.7
							HEMATOCRIT	0.42	L/L		NCS	0.35 - 0.45
							MCH (HbE)	1.73	fmol		NCS	1.59 - 2.00
							MCHC	19.4	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	89.1	fL		NCS	79.4 - 94.8
							THROMBOCYTES	254	/nL		NCS	182 - 369
							LEUKOCYTES	5.4	/nL		NCS	4.0 - 10.0
							NEUTROPHILS	77.2	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	16.6	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	5.2	%		NCS	5.0 - 13.0
							EOSINOPHILS	0.6	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.4	%		NCS	< 1.0
			V4 (WEEK 24)	169	07JUN2011	10:01	ERYTHROCYTES	4.6	/pL		NCS	3.9 - 5.2
							HEMOGLOBIN	7.9	mmol/L		NCS	6.9 - 9.7
							HEMATOCRIT	0.43	L/L		NCS	0.35 - 0.45
							MCH (HbE)	1.71	fmol		NCS	1.59 - 2.00
							MCHC	18.4	mmol/L	LOW	NCS	19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	072	18	V4 (WEEK 24)	169	07JUN2011	10:01	MCV	92.6	fL		NCS	79.4 - 94.8
							THROMBOCYTES	233	/nL		NCS	182 - 369
							LEUKOCYTES	6.8	/nL		NCS	4.0 - 10.0
							NEUTROPHILS	81	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	13.1	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	4.7	%	LOW	NCS	5.0 - 13.0
							EOSINOPHILS	0.9	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.3	%		NCS	< 1.0
			V5 (WEEK 36)	262	08SEP2011	11:03	ERYTHROCYTES	4.6	/pL		NCS	3.9 - 5.2
							HEMOGLOBIN	7.9	mmol/L		NCS	6.9 - 9.7
							HEMATOCRIT	0.42	L/L		NCS	0.35 - 0.45
							MCH (HbE)	1.7	fmol		NCS	1.59 - 2.00
							MCHC	18.8	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	90.3	fL		NCS	79.4 - 94.8
							THROMBOCYTES	206	/nL		NCS	182 - 369
							LEUKOCYTES	6.8	/nL		NCS	4.0 - 10.0
							NEUTROPHILS	81.1	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	14.7	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	3.8	%	LOW	NCS	5.0 - 13.0
							EOSINOPHILS	0.3	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.1	%		NCS	< 1.0
			V6 (WEEK 52)	360	15DEC2011	9:59	ERYTHROCYTES	4.9	/pL		NCS	3.9 - 5.2
							HEMOGLOBIN	8.3	mmol/L		NCS	6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	072	18	V6 (WEEK 52)	360	15DEC2011	9:59	HEMATOCRIT	0.43	L/L		NCS	0.35 - 0.45
							MCH (HbE)	1.71	fmol		NCS	1.59 - 2.00
							MCHC	19.3	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	88.5	fL		NCS	79.4 - 94.8
							THROMBOCYTES	253	/nL		NCS	182 - 369
							LEUKOCYTES	6	/nL		NCS	4.0 - 10.0
							NEUTROPHILS	76.1	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	17.1	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	5.6	%		NCS	5.0 - 13.0
							EOSINOPHILS	1	%		NCS	1.0 - 6.0
							BASOPHILS	0.2	%		NCS	< 1.0
		V7 (WEEK 56)		393	17JAN2012	9:27	ERYTHROCYTES	4.9	/pL		NCS	3.9 - 5.2
							HEMOGLOBIN	8.3	mmol/L		NCS	6.9 - 9.7
							HEMATOCRIT	0.42	L/L		NCS	0.35 - 0.45
							MCH (HbE)	1.7	fmol		NCS	1.59 - 2.00
							MCHC	19.8	mmol/L		NCS	19.8 - 22.3
							MCV	85.7	fL		NCS	79.4 - 94.8
							THROMBOCYTES	229	/nL		NCS	182 - 369
							LEUKOCYTES	6.9	/nL		NCS	4.0 - 10.0
							NEUTROPHILS	78.7	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	14.6	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	5.7	%		NCS	5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW	NCS	1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	072	18	V7 (WEEK 56)	393	17JAN2012	9:27	BASOPHILS	0.3	%		NCS	< 1.0
	079	13	SCREENING	-18	19JUL2010	15:00	ERYTHROCYTES	4.3	/pL			3.9 - 5.2
							HEMOGLOBIN	7.9	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.42	L/L			0.35 - 0.45
							MCH (HbE)	1.84	fmol			1.59 - 2.00
							MCHC	19	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	97	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	267	/nL			182 - 369
							LEUKOCYTES	4.6	/nL			4.0 - 10.0
							NEUTROPHILS	54.4	%			34.0 - 71.0
							LYMPHOCYTES	36.4	%			19.0 - 52.0
							MONOCYTES	6.7	%			5.0 - 13.0
							EOSINOPHILS	1.9	%			1.0 - 6.0
							BASOPHILS	0.6	%			< 1.0
							INR-VALUE	1.04				0.83 - 1.43
							aPTT	32.2	sec			26.0 - 40.0
							QUICK (VENOUS)	94	%			> 70
			V1 (WEEK 0)	1	06AUG2010	9:50	ERYTHROCYTES	4.6	/pL			3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH	NCS	0.35 - 0.45
							MCH (HbE)	1.87	fmol			1.59 - 2.00
							MCHC	18.9	mmol/L	LOW	NCS	19.8 - 22.3

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	079	13	V1 (WEEK 0)	1	06AUG2010	9:50	MCV	98.7	fL	HIGH	NCS	79.4 - 94.8
							THROMBOCYTES	287	/nL			182 - 369
							LEUKOCYTES	5.7	/nL			4.0 - 10.0
							NEUTROPHILS	61.2	%			34.0 - 71.0
							LYMPHOCYTES	31.4	%			19.0 - 52.0
							MONOCYTES	6.1	%			5.0 - 13.0
							EOSINOPHILS	1	%			1.0 - 6.0
							BASOPHILS	0.3	%			< 1.0
			V3 (WEEK 12)	96	09NOV2010	11:40	ERYTHROCYTES	4.6	/pL	3.9 - 5.2		
							HEMOGLOBIN	8.4	mmol/L	6.9 - 9.7		
							HEMATOCRIT	0.42	L/L	0.35 - 0.45		
							MCH (HbE)	1.85	fmol	1.59 - 2.00		
							MCHC	20	mmol/L	19.8 - 22.3		
							MCV	92.6	fL	79.4 - 94.8		
							THROMBOCYTES	306	/nL	182 - 369		
							LEUKOCYTES	5.1	/nL	4.0 - 10.0		
			V4 (WEEK 24)	175	27JAN2011	13:00	NEUTROPHILS	56	%	34.0 - 71.0		
							LYMPHOCYTES	35.6	%	19.0 - 52.0		
							MONOCYTES	7.2	%	5.0 - 13.0		
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0
							ERYTHROCYTES	4.5	/pL			3.9 - 5.2
							HEMOGLOBIN	8.3	mmol/L			6.9 - 9.7

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	079	13	V4 (WEEK 24)	175	27JAN2011	13:00	HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	90.6	fL		79.4 - 94.8
							THROMBOCYTES	349	/nL		182 - 369
							LEUKOCYTES	6.6	/nL		4.0 - 10.0
							NEUTROPHILS	65.8	%		34.0 - 71.0
							LYMPHOCYTES	26.9	%		19.0 - 52.0
							MONOCYTES	6.5	%		5.0 - 13.0
							EOSINOPHILS	0.5	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V5 (WEEK 36)	249	11APR2011	11:45	ERYTHROCYTES	4.5	/pL		3.9 - 5.2
							HEMOGLOBIN	8.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.83	fmol		1.59 - 2.00
							MCHC	19.2	mmol/L	LOW NCS	19.8 - 22.3
							MCV	95.3	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	299	/nL		182 - 369
							LEUKOCYTES	5.4	/nL		4.0 - 10.0
							NEUTROPHILS	56.8	%		34.0 - 71.0
							LYMPHOCYTES	35.6	%		19.0 - 52.0
							MONOCYTES	6.5	%		5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW NCS	1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	079	13	V5 (WEEK 36)	249	11APR2011	11:45	BASOPHILS	0.4	%		< 1.0
			V6 (WEEK 52)	320	21JUN2011	11:15	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	8.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	19.3	mmol/L	LOW NCS	19.8 - 22.3
							MCV	95.9	fL	HIGH NCS	79.4 - 94.8
							THROMBOCYTES	300	/nL		182 - 369
							LEUKOCYTES	6	/nL		4.0 - 10.0
							NEUTROPHILS	67.7	%		34.0 - 71.0
							LYMPHOCYTES	25.2	%		19.0 - 52.0
							MONOCYTES	6.1	%		5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
			V7 (WEEK 56)	348	19JUL2011	14:35	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45
							MCH (HbE)	1.86	fmol		1.59 - 2.00
							MCHC	19.7	mmol/L	LOW NCS	19.8 - 22.3
							MCV	94.6	fL		79.4 - 94.8
							THROMBOCYTES	291	/nL		182 - 369
							LEUKOCYTES	5.8	/nL		4.0 - 10.0
							NEUTROPHILS	56.7	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	079	13	V7 (WEEK 56)	348	19JUL2011	14:35	LYMPHOCYTES	35.5	%		19.0 - 52.0
							MONOCYTES	6.6	%		5.0 - 13.0
							EOSINOPHILS	1	%		1.0 - 6.0
							BASOPHILS	0.2	%		< 1.0
	082	17	SCREENING	-8	06OCT2010	11:00	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	8.7	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.44	L/L		0.40 - 0.50
							MCH (HbE)	1.81	fmol		1.59 - 2.00
							MCHC	19.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	92.3	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	169	/nL		163 - 337
							LEUKOCYTES	4.7	/nL		4.2 - 9.1
							NEUTROPHILS	57.6	%		34.0 - 68.0
							LYMPHOCYTES	32.2	%		22.0 - 53.0
							MONOCYTES	6.6	%		5.0 - 12.0
							EOSINOPHILS	3.4	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
							INR-VALUE	1.33			0.83 - 1.43
							aPTT	44.3	sec	HIGH NCS	26.0 - 40.0
							QUICK (VENOUS)	67	%	LOW NCS	> 70
							ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	8.9	mmol/L		8.5 - 10.9
			V1 (WEEK 0)	1	14OCT2010	9:00					

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	082	17	V1 (WEEK 0)	1	14OCT2010	9:00	HEMATOCRIT	0.45	L/L	HIGH	NCS	0.40 - 0.50
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	19.9	mmol/L			19.8 - 22.3
							MCV	93.1	fL			79.0 - 92.2
							THROMBOCYTES	166	/nL			163 - 337
							LEUKOCYTES	5.7	/nL			4.2 - 9.1
							NEUTROPHILS	60.4	%			34.0 - 68.0
							LYMPHOCYTES	30.8	%			22.0 - 53.0
							MONOCYTES	6.5	%			5.0 - 12.0
							EOSINOPHILS	2.1	%			1.0 - 7.0
							BASOPHILS	0.2	%			< 1.0
		V3 (WEEK 12)	84	05JAN2011	12:30	ERYTHROCYTES	5	/pL	LOW	NCS	4.6 - 6.1	
						HEMOGLOBIN	9	mmol/L			8.5 - 10.9	
						HEMATOCRIT	0.46	L/L			0.40 - 0.50	
						MCH (HbE)	1.82	fmol			1.59 - 2.00	
						MCHC	19.5	mmol/L			19.8 - 22.3	
						MCV	93.1	fL			79.0 - 92.2	
						THROMBOCYTES	155	/nL			163 - 337	
						LEUKOCYTES	6.4	/nL			4.2 - 9.1	
						NEUTROPHILS	55.9	%			34.0 - 68.0	
						LYMPHOCYTES	33.9	%			22.0 - 53.0	
						MONOCYTES	6.6	%			5.0 - 12.0	
						EOSINOPHILS	3.3	%			1.0 - 7.0	

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Listing 16.2.8.3: Hematology/Coagulation

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	082	17	V3 (WEEK 12)	84	05JAN2011	12:30	BASOPHILS	0.3	%			< 1.0
			V4 (WEEK 24)	175	06APR2011	9:20	ERYTHROCYTES	5.9	/pL			4.6 - 6.1
							HEMOGLOBIN	10.9	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.56	L/L	HIGH	NCS	0.40 - 0.50
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	19.7	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	94.4	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	145	/nL	LOW	NCS	163 - 337
							LEUKOCYTES	7	/nL			4.2 - 9.1
							NEUTROPHILS	56.9	%			34.0 - 68.0
							LYMPHOCYTES	31.9	%			22.0 - 53.0
							MONOCYTES	7.5	%			5.0 - 12.0
							EOSINOPHILS	3.6	%			1.0 - 7.0
							BASOPHILS	0.1	%			< 1.0
			V5 (WEEK 36)	252	22JUN2011	11:15	ERYTHROCYTES	4.6	/pL			4.6 - 6.1
							HEMOGLOBIN	8.9	mmol/L			8.5 - 10.9
							HEMATOCRIT	0.48	L/L			0.40 - 0.50
							MCH (HbE)	1.93	fmol			1.59 - 2.00
							MCHC	18.8	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	103	fL	HIGH	NCS	79.0 - 92.2
							THROMBOCYTES	157	/nL	LOW	NCS	163 - 337
							LEUKOCYTES	5.4	/nL			4.2 - 9.1
							NEUTROPHILS	55.5	%			34.0 - 68.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	082	17	V5 (WEEK 36)	252	22JUN2011	11:15	LYMPHOCYTES	34.6	%		22.0 - 53.0
			V6 (WEEK 52)	364	12OCT2011	9:15	MONOCYTES	6.5	%		5.0 - 12.0
							EOSINOPHILS	3.2	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
							ERYTHROCYTES	4.9	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.46	L/L		0.40 - 0.50
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	19.6	mmol/L	LOW NCS	19.8 - 22.3
							MCV	94.5	fL	HIGH NCS	79.0 - 92.2
							THROMBOCYTES	156	/nL	LOW NCS	163 - 337
							LEUKOCYTES	5.4	/nL		4.2 - 9.1
							NEUTROPHILS	56	%		34.0 - 68.0
							LYMPHOCYTES	32.1	%		22.0 - 53.0
							MONOCYTES	7.2	%		5.0 - 12.0
							EOSINOPHILS	4.5	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
			V7 (WEEK 56)	407	24NOV2011	9:20	ERYTHROCYTES	4.8	/pL		4.6 - 6.1
							HEMOGLOBIN	9.1	mmol/L		8.5 - 10.9
							HEMATOCRIT	0.45	L/L		0.40 - 0.50
							MCH (HbE)	1.88	fmol		1.59 - 2.00
							MCHC	20	mmol/L		19.8 - 22.3
							MCV	94	fL	HIGH NCS	79.0 - 92.2

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant	range
Placebo	082	17	V7 (WEEK 56)	407	24NOV2011	9:20	THROMBOCYTES	153	/nL	LOW NCS	163 - 337
							LEUKOCYTES	5.5	/nL		4.2 - 9.1
							NEUTROPHILS	56.9	%		34.0 - 68.0
							LYMPHOCYTES	32.1	%		22.0 - 53.0
							MONOCYTES	7.2	%		5.0 - 12.0
							EOSINOPHILS	3.6	%		1.0 - 7.0
							BASOPHILS	0.2	%		< 1.0
	084	17	SCREENING	-9	08NOV2010	10:00	ERYTHROCYTES	5.2	/pL		3.9 - 5.2
							HEMOGLOBIN	8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.54	fmol	LOW NCS	1.59 - 2.00
							MCHC	18.7	mmol/L	LOW NCS	19.8 - 22.3
							MCV	82.3	fL		79.4 - 94.8
							THROMBOCYTES	288	/nL		182 - 369
							LEUKOCYTES	5.7	/nL		4.0 - 10.0
							NEUTROPHILS	53.7	%		34.0 - 71.0
							LYMPHOCYTES	37.6	%		19.0 - 52.0
							MONOCYTES	6.8	%		5.0 - 13.0
							EOSINOPHILS	1.6	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
							INR-VALUE	1.23			0.83 - 1.43
							aPTT	46.3	sec	HIGH NCS	26.0 - 40.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference	
					Date	Time				/Low ficant	range
Placebo	084	17	SCREENING V1 (WEEK 0)	-9 1	08NOV2010 17NOV2010	10:00 9:15	QUICK (VENOUS)	74	%		> 70
							ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	7.5	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.38	L/L		0.35 - 0.45
							MCH (HbE)	1.53	fmol	LOW NCS	1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	78.5	fL	LOW NCS	79.4 - 94.8
							THROMBOCYTES	244	/nL		182 - 369
							LEUKOCYTES	6.1	/nL		4.0 - 10.0
							NEUTROPHILS	49.9	%		34.0 - 71.0
							LYMPHOCYTES	43.2	%		19.0 - 52.0
							MONOCYTES	5.9	%		5.0 - 13.0
							EOSINOPHILS	0.7	%	LOW NCS	1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V3 (WEEK 12)	84	08FEB2011	10:20	ERYTHROCYTES	5.2	/pL		3.9 - 5.2
							HEMOGLOBIN	8.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.57	fmol	LOW NCS	1.59 - 2.00
							MCHC	18.9	mmol/L	LOW NCS	19.8 - 22.3
							MCV	83.2	fL		79.4 - 94.8
							THROMBOCYTES	299	/nL		182 - 369
							LEUKOCYTES	5.5	/nL		4.0 - 10.0
							NEUTROPHILS	44	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	084	17	V3 (WEEK 12)	84	08FEB2011	10:20	LYMPHOCYTES	47.5	%		19.0 - 52.0
							MONOCYTES	6.6	%		5.0 - 13.0
							EOSINOPHILS	1.5	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
			V4 (WEEK 24)	175	10MAY2011	10:45	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	7.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.54	fmol	LOW NCS	1.59 - 2.00
							MCHC	18.9	mmol/L	LOW NCS	19.8 - 22.3
							MCV	81.2	fL		79.4 - 94.8
							THROMBOCYTES	243	/nL		182 - 369
							LEUKOCYTES	5.5	/nL		4.0 - 10.0
							NEUTROPHILS	47.7	%		34.0 - 71.0
							LYMPHOCYTES	43.8	%		19.0 - 52.0
							MONOCYTES	6.7	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
			V5 (WEEK 36)	259	02AUG2011	11:15	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.41	L/L		0.35 - 0.45
							MCH (HbE)	1.59	fmol		1.59 - 2.00
							MCHC	19	mmol/L	LOW NCS	19.8 - 22.3
							MCV	83.5	fL		79.4 - 94.8

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	084	17	V5 (WEEK 36)	259	02AUG2011	11:15	THROMBOCYTES	202	/nL		182 - 369
							LEUKOCYTES	5.8	/nL		4.0 - 10.0
							NEUTROPHILS	44	%		34.0 - 71.0
							LYMPHOCYTES	47.7	%		19.0 - 52.0
							MONOCYTES	6.6	%		5.0 - 13.0
							EOSINOPHILS	1.4	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V6 (WEEK 52)	371	22NOV2011	11:30	ERYTHROCYTES		/pL		3.9 - 5.2
							HEMOGLOBIN		mmol/L		6.9 - 9.7
							HEMATOCRIT		L/L		0.35 - 0.45
							MCH (HbE)		fmol		1.59 - 2.00
							MCHC		mmol/L		19.8 - 22.3
							MCV		fL		79.4 - 94.8
							THROMBOCYTES		/nL		182 - 369
							LEUKOCYTES		/nL		4.0 - 10.0
							NEUTROPHILS		%		34.0 - 71.0
							LYMPHOCYTES		%		19.0 - 52.0
							MONOCYTES		%		5.0 - 13.0
							EOSINOPHILS		%		1.0 - 6.0
							BASOPHILS		%		< 1.0
			V7 (WEEK 56)	394	15DEC2011	9:32	ERYTHROCYTES		/pL		3.9 - 5.2
							HEMOGLOBIN		mmol/L		6.9 - 9.7
							HEMATOCRIT		L/L		0.35 - 0.45

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	084	17	V7 (WEEK 56)	394	15DEC2011	9:32	MCH (HbE)		fmol		1.59 - 2.00
							MCHC		mmol/L		19.8 - 22.3
							MCV		fL		79.4 - 94.8
							THROMBOCYTES		/nL		182 - 369
							LEUKOCYTES		/nL		4.0 - 10.0
							NEUTROPHILS		%		34.0 - 71.0
							LYMPHOCYTES		%		19.0 - 52.0
							MONOCYTES		%		5.0 - 13.0
							EOSINOPHILS		%		1.0 - 6.0
							BASOPHILS		%		< 1.0
	086	21	SCREENING	-24	04OCT2010	11:05	ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.47	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	93.2	fL		79.4 - 94.8
							THROMBOCYTES	311	/nL		182 - 369
							LEUKOCYTES	7.5	/nL		4.0 - 10.0
							NEUTROPHILS	65.6	%		34.0 - 71.0
							LYMPHOCYTES	23.9	%		19.0 - 52.0
							MONOCYTES	8.5	%		5.0 - 13.0
							EOSINOPHILS	1.5	%		1.0 - 6.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	086	21	SCREENING	-24	04OCT2010	11:05	BASOPHILS	0.5	%		< 1.0
							INR-VALUE	0.98			0.83 - 1.43
							aPTT	36.3	sec		26.0 - 40.0
							QUICK (VENOUS)	103	%		> 70
			V1 (WEEK 0)	1	28OCT2010	14:05	ERYTHROCYTES	4.7	/pL		3.9 - 5.2
							HEMOGLOBIN	8.7	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.43	L/L		0.35 - 0.45
							MCH (HbE)	1.85	fmol		1.59 - 2.00
							MCHC	20.5	mmol/L		19.8 - 22.3
							MCV	90.1	fL		79.4 - 94.8
							THROMBOCYTES	284	/nL		182 - 369
							LEUKOCYTES	8.6	/nL		4.0 - 10.0
							NEUTROPHILS	66.1	%		34.0 - 71.0
							LYMPHOCYTES	23.4	%		19.0 - 52.0
							MONOCYTES	8.5	%		5.0 - 13.0
							EOSINOPHILS	1.5	%		1.0 - 6.0
			V3 (WEEK 12)	83	18JAN2011	11:30	BASOPHILS	0.5	%		< 1.0
							ERYTHROCYTES	5	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.82	fmol		1.59 - 2.00
							MCHC	20.2	mmol/L		19.8 - 22.3
							MCV	90.2	fL		79.4 - 94.8

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	086	21	V3 (WEEK 12)	83	18JAN2011	11:30	THROMBOCYTES	315	/nL	LOW NCS	182 - 369
							LEUKOCYTES	7.4	/nL		4.0 - 10.0
							NEUTROPHILS	65.5	%		34.0 - 71.0
							LYMPHOCYTES	22.9	%		19.0 - 52.0
							MONOCYTES	10.5	%		5.0 - 13.0
							EOSINOPHILS	0.7	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
			V4 (WEEK 24)	167	12APR2011	11:55	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.45	L/L		0.35 - 0.45
							MCH (HbE)	1.87	fmol		1.59 - 2.00
							MCHC	20.6	mmol/L		19.8 - 22.3
							MCV	90.8	fL		79.4 - 94.8
							THROMBOCYTES	332	/nL		182 - 369
							LEUKOCYTES	8.9	/nL		4.0 - 10.0
							NEUTROPHILS	66.9	%		34.0 - 71.0
							LYMPHOCYTES	22.8	%		19.0 - 52.0
							MONOCYTES	8.8	%		5.0 - 13.0
							EOSINOPHILS	1.2	%		1.0 - 6.0
							BASOPHILS	0.3	%		< 1.0
			V5 (WEEK 36)	251	05JUL2011	11:57	ERYTHROCYTES	4.8	/pL		3.9 - 5.2
							HEMOGLOBIN	8.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.44	L/L		0.35 - 0.45

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
Placebo	086	21	V5 (WEEK 36)	251	05JUL2011	11:57	MCH (HbE)	1.8	fmol			1.59 - 2.00
							MCHC	19.5	mmol/L	LOW	NCS	19.8 - 22.3
							MCV	92.7	fL			79.4 - 94.8
							THROMBOCYTES	287	/nL			182 - 369
							LEUKOCYTES	8.3	/nL			4.0 - 10.0
							NEUTROPHILS	74.9	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	15.5	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	8.2	%			5.0 - 13.0
							EOSINOPHILS	1.2	%			1.0 - 6.0
							BASOPHILS	0.2	%			< 1.0
			V6 (WEEK 52)	363	25OCT2011	11:30	ERYTHROCYTES	5	/pL			3.9 - 5.2
							HEMOGLOBIN	9.2	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.45	L/L			0.35 - 0.45
							MCH (HbE)	1.85	fmol			1.59 - 2.00
							MCHC	20.4	mmol/L			19.8 - 22.3
							MCV	90.8	fL			79.4 - 94.8
							THROMBOCYTES	365	/nL			182 - 369
							LEUKOCYTES	8.9	/nL			4.0 - 10.0
							NEUTROPHILS	73.8	%	HIGH	NCS	34.0 - 71.0
							LYMPHOCYTES	17.4	%	LOW	NCS	19.0 - 52.0
							MONOCYTES	7.6	%			5.0 - 13.0
							EOSINOPHILS	0.8	%	LOW	NCS	1.0 - 6.0
							BASOPHILS	0.4	%			< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	086	21	V7 (WEEK 56)	391	22NOV2011	10:10	ERYTHROCYTES	4.9	/pL		3.9 - 5.2
							HEMOGLOBIN	9.1	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.46	L/L	HIGH NCS	0.35 - 0.45
							MCH (HbE)	1.84	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	92.9	fL		79.4 - 94.8
							THROMBOCYTES	313	/nL		182 - 369
							LEUKOCYTES	7.4	/nL		4.0 - 10.0
							NEUTROPHILS	69.2	%		34.0 - 71.0
							LYMPHOCYTES	20.5	%		19.0 - 52.0
							MONOCYTES	8.8	%		5.0 - 13.0
							EOSINOPHILS	1.1	%		1.0 - 6.0
							BASOPHILS	0.4	%		< 1.0
	088	16	SCREENING	-9	30NOV2010	10:00	ERYTHROCYTES	4.5	/pL		3.9 - 5.2
							HEMOGLOBIN	7.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.38	L/L		0.35 - 0.45
							MCH (HbE)	1.67	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	84.4	fL		79.4 - 94.8
							THROMBOCYTES	297	/nL		182 - 369
							LEUKOCYTES	6.5	/nL		4.0 - 10.0
							NEUTROPHILS	62.3	%		34.0 - 71.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	088	16	SCREENING	-9	30NOV2010	10:00	LYMPHOCYTES	24.8	%		19.0 - 52.0
							MONOCYTES	8.9	%		5.0 - 13.0
							EOSINOPHILS	3.2	%		1.0 - 6.0
							BASOPHILS	0.8	%		< 1.0
							INR-VALUE	1.08			0.83 - 1.43
							aPTT	32	sec		26.0 - 40.0
			V1 (WEEK 0)	1	09DEC2010	9:05	QUICK (VENOUS)	88	%		> 70
							ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	7.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45
							MCH (HbE)	1.66	fmol		1.59 - 2.00
							MCHC	19.5	mmol/L	LOW NCS	19.8 - 22.3
							MCV	85.2	fL		79.4 - 94.8
							THROMBOCYTES	350	/nL		182 - 369
							LEUKOCYTES	6.3	/nL		4.0 - 10.0
							NEUTROPHILS	59.8	%		34.0 - 71.0
							LYMPHOCYTES	29.2	%		19.0 - 52.0
							MONOCYTES	7.8	%		5.0 - 13.0
							EOSINOPHILS	2.6	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
			V3 (WEEK 12)	83	01MAR2011	10:00	ERYTHROCYTES	4.6	/pL		3.9 - 5.2
							HEMOGLOBIN	7.6	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High signi- /Low	ficant	
Placebo	088	16	V3 (WEEK 12)	83	01MAR2011	10:00	MCH (HbE)	1.66	fmol	LOW	NCS	1.59 - 2.00
							MCHC	19.6	mmol/L			19.8 - 22.3
							MCV	84.6	fL			79.4 - 94.8
							THROMBOCYTES	314	/nL			182 - 369
							LEUKOCYTES	4.6	/nL			4.0 - 10.0
							NEUTROPHILS	54.6	%			34.0 - 71.0
							LYMPHOCYTES	33.8	%			19.0 - 52.0
							MONOCYTES	8	%			5.0 - 13.0
							EOSINOPHILS	3	%			1.0 - 6.0
							BASOPHILS	0.6	%			< 1.0
			V4 (WEEK 24)	162	19MAY2011	9:30	ERYTHROCYTES	4.5	/pL			3.9 - 5.2
							HEMOGLOBIN	7.6	mmol/L			6.9 - 9.7
							HEMATOCRIT	0.4	L/L			0.35 - 0.45
							MCH (HbE)	1.69	fmol			1.59 - 2.00
							MCHC	18.8	mmol/L			19.8 - 22.3
							MCV	89.7	fL			79.4 - 94.8
							THROMBOCYTES	259	/nL			182 - 369
							LEUKOCYTES	6.3	/nL			4.0 - 10.0
							NEUTROPHILS	56.3	%			34.0 - 71.0
							LYMPHOCYTES	34.3	%			19.0 - 52.0
							MONOCYTES	7	%			5.0 - 13.0
							EOSINOPHILS	1.9	%			1.0 - 6.0
							BASOPHILS	0.5	%			< 1.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	088	16	V5 (WEEK 36)	264	29AUG2011	9:35	ERYTHROCYTES	4.3	/pL	LOW NCS	3.9 - 5.2
							HEMOGLOBIN	7.4	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45
							MCH (HbE)	1.7	fmol		1.59 - 2.00
							MCHC	19	mmol/L		19.8 - 22.3
							MCV	89.2	fL		79.4 - 94.8
							THROMBOCYTES	306	/nL		182 - 369
							LEUKOCYTES	5.1	/nL		4.0 - 10.0
							NEUTROPHILS	48.9	%		34.0 - 71.0
							LYMPHOCYTES	41.1	%		19.0 - 52.0
							MONOCYTES	5.7	%		5.0 - 13.0
							EOSINOPHILS	3.7	%		1.0 - 6.0
							BASOPHILS	0.6	%		< 1.0
			V7 (WEEK 56)	404	16JAN2012	9:30	ERYTHROCYTES	4.4	/pL		3.9 - 5.2
							HEMOGLOBIN	7.8	mmol/L		6.9 - 9.7
							HEMATOCRIT	0.39	L/L		0.35 - 0.45
							MCH (HbE)	1.75	fmol		1.59 - 2.00
							MCHC	19.8	mmol/L		19.8 - 22.3
							MCV	88.3	fL		79.4 - 94.8
							THROMBOCYTES	242	/nL		182 - 369
							LEUKOCYTES	3.3	/nL	LOW NCS	4.0 - 10.0
							NEUTROPHILS	25.5	%	LOW NCS	34.0 - 71.0
							LYMPHOCYTES	55.9	%	HIGH NCS	19.0 - 52.0

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Listing 16.2.8.3: Hematology/Coagulation

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Treat- ment	Random No.	Site ID	Visit	Actual day	Blood sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	088	16	V7 (WEEK 56)	404	16JAN2012	9:30	MONOCYTES	12.3	%		5.0 - 13.0
							EOSINOPHILS	4.8	%		1.0 - 6.0
							BASOPHILS	1.5	%	HIGH NCS	< 1.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	002	1	SCREENING	-7	16APR2009	10:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V1 (WEEK 0)	1	23APR2009	8:55	LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V3 (WEEK 12)	85	16JUL2009	8:30	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V4 (WEEK 24)	169	08OCT2009	10:35	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	002	1	V4 (WEEK 24)	169	08OCT2009	10:35	LEUKOCYTES	NEGATIVE	/µL		< 20
			V5 (WEEK 36)	258	05JAN2010	10:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V6 (WEEK 52)	365	22APR2010	10:10	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V7 (WEEK 56)	393	20MAY2010	9:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	004	1	SCREENING	-29	17JUN2009	11:40	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	004	1	SCREENING	-29	17JUN2009	11:40	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
		V1 (WEEK 0)	1	16JUL2009	10:00	KETONES	NEGATIVE	mmol/L		< 0.5	
						BLOOD	NEGATIVE	/μL		< 5	
						LEUKOCYTES	NEGATIVE	/μL		< 20	
						pH-VALUE	6.0		5.0 - 7.0		
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
		V3 (WEEK 12)	92	15OCT2009	14:50	KETONES	NEGATIVE	mmol/L		< 0.5	
						BLOOD	NEGATIVE	/μL		< 5	
						LEUKOCYTES	NEGATIVE	/μL		< 20	
						pH-VALUE	6.0		5.0 - 7.0		
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
					KETONES	NEGATIVE	mmol/L		< 0.5		
					BLOOD	NEGATIVE	/μL		< 5		
					LEUKOCYTES	NEGATIVE	/μL		< 20		
006	2	SCREENING	-32	25JAN2010	8:30	pH-VALUE	6.5		5.0 - 7.0		
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	
						BLOOD	NEGATIVE	/μL		< 5	
						LEUKOCYTES	NEGATIVE	/μL		< 20	
		V1 (WEEK 0)	1	26FEB2010	9:00	pH-VALUE	7.0		5.0 - 7.0		

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	006	2	V1 (WEEK 0)	1	26FEB2010	9:00	PROTEIN	NEGATIVE	mg/L		< 150
			V3 (WEEK 12)	85	21MAY2010	9:15	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	8.0		HIGH NCS	5.0 - 7.0
			V4 (WEEK 24)	169	13AUG2010	9:15	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	364	24FEB2011	8:25	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL	HIGH NCS	< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	006	2	V7 (WEEK 56)	390	22MAR2011	8:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	010	1	SCREENING	-26	25JUN2009	9:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		V1 (WEEK 0)		1	21JUL2009	11:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
		V3 (WEEK 12)		85	13OCT2009	10:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	010	1	V3 (WEEK 12)	85	13OCT2009	10:45	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	012	1	SCREENING	-32	17JUN2010	12:20	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V1 (WEEK 0)	1	19JUL2010	10:00	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V3 (WEEK 12)	88	14OCT2010	9:15	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V6 (WEEK 52)	361	14JUL2011	10:25	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	012	1	V6 (WEEK 52)	361	14JUL2011	10:25	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.5			5.0 - 7.0
		V7 (WEEK 56)		396	18AUG2011	12:15	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	014	4	SCREENING	-26	07OCT2009	13:45	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
		V1 (WEEK 0)		1	02NOV2009	10:00	LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	014	4	V3 (WEEK 12)	85	25JAN2010	11:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
			V4 (WEEK 24)	172	22APR2010	10:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
			V6 (WEEK 52)	361	28OCT2010	13:30	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
			V7 (WEEK 56)	396	02DEC2010	11:35	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	014	4	V7 (WEEK 56)	396	02DEC2010	11:35	LEUKOCYTES	NEGATIVE	/µL		< 20
	015	4	SCREENING	-32	21JAN2010	12:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V1 (WEEK 0)	1	22FEB2010	11:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
			V3 (WEEK 12)	85	17MAY2010	10:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
			V4 (WEEK 24)	162	02AUG2010	9:40	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	015	4	V4 (WEEK 24)	162	02AUG2010	9:40	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V5 (WEEK 36)	248	27OCT2010	11:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	500	/μL	HIGH NCS	< 20
			V6 (WEEK 52)	365	21FEB2011	12:30	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	500	/μL	HIGH NCS	< 20
			V7 (WEEK 56)	394	22MAR2011	11:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
	017	5	SCREENING	-22	14JUL2009	10:30	pH-VALUE	6.5			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	017	5	SCREENING	-22	14JUL2009	10:30	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V1 (WEEK 0)	1	05AUG2009	9:10	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
			V3 (WEEK 12)	85	28OCT2009	8:45	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V4 (WEEK 24)	169	20JAN2010	9:00	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	25	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	017	5	V5 (WEEK 36)	252	13APR2010	10:45	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V6 (WEEK 52)	364	03AUG2010	11:00	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V7 (WEEK 56)	392	31AUG2010	9:00	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	25	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	019	5	SCREENING	-21	18NOV2009	12:55	pH-VALUE	5.0			5.0 - 7.0
							KETONES	NEGATIVE	mmol/L		< 0.5
							BILIRUBIN	NEGATIVE	µmol/l		< 3.4
							BLOOD	NEGATIVE	/µL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	019	5	V1 (WEEK 0)	1	09DEC2009	9:00	pH-VALUE	5.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	
			V3 (WEEK 12)	85	03MAR2010	9:00	LEUKOCYTES	NEGATIVE	/μL	< 20	
							pH-VALUE	5.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
			V4 (WEEK 24)	168	25MAY2010	9:00	BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
							pH-VALUE	5.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
			V6 (WEEK 52)	364	07DEC2010	9:00	KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
							pH-VALUE	5.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	019	5	V6 (WEEK 52)	364	07DEC2010	9:00	LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V7 (WEEK 56)	399	11JAN2011	9:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	023	4	SCREENING	-19	01JUL2010	13:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V1 (WEEK 0)		1	20JUL2010	11:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V3 (WEEK 12)		86	13OCT2010	9:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
ACI-91	023	4	V3 (WEEK 12)	86	13OCT2010	9:45	KETONES	NEGATIVE	mmol/L	< 0.5	
			V4 (WEEK 24)	177	12JAN2011	13:00	BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
							pH-VALUE	7.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	
			V5 (WEEK 36)	245	21MAR2011	10:00	LEUKOCYTES	NEGATIVE	/μL	< 20	
							pH-VALUE	5.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
			V6 (WEEK 52)	364	18JUL2011	10:10	pH-VALUE	7.0		5.0 - 7.0	
							PROTEIN	NEGATIVE	mg/L	< 150	
							GLUCOSE	NEGATIVE	mmol/L	< 0.8	
							KETONES	NEGATIVE	mmol/L	< 0.5	
							BLOOD	NEGATIVE	/μL	< 5	
							LEUKOCYTES	NEGATIVE	/μL	< 20	
							pH-VALUE	5.0		5.0 - 7.0	
			V7 (WEEK 56)	388	11AUG2011	12:45	PROTEIN	NEGATIVE	mg/L	< 150	

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	023	4	V7 (WEEK 56)	388	11AUG2011	12:45	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	027	20	SCREENING	-21	30SEP2010	10:40	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
		V1 (WEEK 0)		1	21OCT2010	9:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V3 (WEEK 12)		92	20JAN2011	11:15	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	027	20	V4 (WEEK 24)	174	12APR2011	10:35	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH CS	< 0.5
							BLOOD	10	/µL	HIGH CS	< 5
			V5 (WEEK 36)	259	06JUL2011	9:30	LEUKOCYTES	100	/µL	HIGH CS	< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V6 (WEEK 52)	370	25OCT2011	8:25	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V7 (WEEK 56)	407	01DEC2011	10:15	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	100	/µL	HIGH CS	< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	027	20	V7 (WEEK 56)	407	01DEC2011	10:15	LEUKOCYTES	25	/µL	HIGH NCS	< 20
	030	8	SCREENING	-7	18MAR2010	13:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V1 (WEEK 0)	1	25MAR2010	11:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V3 (WEEK 12)	85	17JUN2010	10:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH CS	< 20
			V4 (WEEK 24)	163	03SEP2010	11:45	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	030	8	V4 (WEEK 24)	163	03SEP2010	11:45	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V6 (WEEK 52)	355	14MAR2011	14:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	100	/μL	HIGH CS	< 20
			V7 (WEEK 56)	383	11APR2011	11:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
	032	8	SCREENING	-10	08NOV2010	11:40	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	18NOV2010	15:00	pH-VALUE	7.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	032	8	V1 (WEEK 0)	1	18NOV2010	15:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V3 (WEEK 12)	82	07FEB2011	12:30	pH-VALUE	8.0		HIGH NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	033	9	SCREENING	-7	28OCT2009	11:30	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
			V1 (WEEK 0)	1	04NOV2009	8:20	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	033	9	V1 (WEEK 0)	1	04NOV2009	8:20	LEUKOCYTES	NEGATIVE	/µL		< 20
			V3 (WEEK 12)	78	20JAN2010	9:10	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V4 (WEEK 24)	169	21APR2010	9:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V5 (WEEK 36)	261	22JUL2010	8:45	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V6 (WEEK 52)	372	10NOV2010	8:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	033	9	V6 (WEEK 52)	372	10NOV2010	8:20	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V7 (WEEK 56)		398	06DEC2010	8:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
	042	12	SCREENING	-29	16DEC2009	9:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V1 (WEEK 0)		1	14JAN2010	9:45	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
		V3 (WEEK 12)		126	19MAY2010	9:00	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	042	12	V3 (WEEK 12)	126	19MAY2010	9:00	GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V4 (WEEK 24)	168	30JUN2010	12:45	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	7.0			5.0 - 7.0
			V5 (WEEK 36)	252	22SEP2010	9:05	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
			V6 (WEEK 52)	364	12JAN2011	13:00	LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
			V7 (WEEK 56)	391	08FEB2011	9:30	pH-VALUE	5.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	042	12	V7 (WEEK 56)	391	08FEB2011	9:30	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	500	/μL	HIGH NCS	< 20
	043	12	SCREENING	-28	21OCT2009	9:45	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	2.8	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V1 (WEEK 0)	1	18NOV2009	13:45	LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							KETONES	NEGATIVE	mmol/L		< 0.5
							BILIRUBIN	NEGATIVE	μmol/l		< 3.4
							BLOOD	NEGATIVE	/μL		< 5
			V3 (WEEK 12)	85	10FEB2010	12:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
	V4 (WEEK 24)	176	12MAY2010	13:00	PROTEIN	NEGATIVE	mg/L		< 150		
					GLUCOSE	NEGATIVE	mmol/L		< 0.8		
					KETONES	NEGATIVE	mmol/L		< 0.5		
					BLOOD	NEGATIVE	/μL		< 5		

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	043	12	V4 (WEEK 24)	176	12MAY2010	13:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	046	11	SCREENING	-28	14DEC2009	10:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	750	mg/L	HIGH CS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
		V1 (WEEK 0)		1	11JAN2010	12:00	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
		V3 (WEEK 12)		87	07APR2010	11:30	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	046	11	V3 (WEEK 12)	87	07APR2010	11:30	LEUKOCYTES	NEGATIVE	/μL		< 20
			V4 (WEEK 24)	178	07JUL2010	11:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	367	12JAN2011	9:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	2.8	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V7 (WEEK 56)	393	07FEB2011	9:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH CS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
	048	11	SCREENING	-5	17NOV2010	12:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	048	11	SCREENING	-5	17NOV2010	12:30	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V1 (WEEK 0)	1	22NOV2010	10:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V3 (WEEK 12)	86	15FEB2011	12:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V4 (WEEK 24)	176	16MAY2011	11:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V5 (WEEK 36)	247	26JUL2011	10:55	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin.	Reference range
					Date	Time				High signi- /Low ficant	
ACI-91	048	11	V5 (WEEK 36)	247	26JUL2011	10:55	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		V6 (WEEK 52)	360	16NOV2011	10:10	pH-VALUE	6.5			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	
						BLOOD	NEGATIVE	/μL		< 5	
		V7 (WEEK 56)	395	21DEC2011	11:35	LEUKOCYTES	NEGATIVE	/μL		< 20	
						pH-VALUE	5.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	
	050	21	SCREENING	-51	06SEP2010	14:30	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
LEUKOCYTES	NEGATIVE	/μL		< 20							

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	050	21	V1 (WEEK 0)	1	27OCT2010	11:45	pH-VALUE	5.0			5.0 - 7.0
			V3 (WEEK 12)	83	17JAN2011	11:15	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
			V4 (WEEK 24)	167	11APR2011	11:20	pH-VALUE	5.0			5.0 - 7.0
			V5 (WEEK 36)	251	04JUL2011	11:50	PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	050	21	V5 (WEEK 36)	251	04JUL2011	11:50	LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V6 (WEEK 52)	363	24OCT2011	10:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
		21	V7 (WEEK 56)	391	21NOV2011	9:30	LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
	052	21	SCREENING	-52	06SEP2010	14:15	LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
		21	V1 (WEEK 0)	1	28OCT2010	8:15	LEUKOCYTES	100	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
		21					GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	052	21	V1 (WEEK 0)	1	28OCT2010	8:15	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V3 (WEEK 12)	82	17JAN2011	10:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
			V4 (WEEK 24)	166	11APR2011	10:40	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V5 (WEEK 36)	250	04JUL2011	9:24	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
			V6 (WEEK 52)	362	24OCT2011	14:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	052	21	V6 (WEEK 52)	362	24OCT2011	14:45	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
		V7 (WEEK 56)		390	21NOV2011	11:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
	055	5	SCREENING	-21	08MAR2010	11:30	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V1 (WEEK 0)	1	29MAR2010	9:30	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20

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Listing 16.2.8.4: Urinalysis

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	055	5	V6 (WEEK 52)	30	27APR2010	9:15	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	057	1	SCREENING	-21	29JUL2010	10:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
		V1 (WEEK 0)		1	19AUG2010	11:10	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
		V3 (WEEK 12)		82	08NOV2010	10:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	057	1	V3 (WEEK 12)	82	08NOV2010	10:00	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
		V4 (WEEK 24)		170	04FEB2011	9:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
	066	16	SCREENING	-31	09AUG2010	10:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
		V1 (WEEK 0)		1	09SEP2010	9:30	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
	V3 (WEEK 12)	83		30	30NOV2010	9:30	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	066	16	V3 (WEEK 12)	83	30NOV2010	9:30	GLUCOSE	2.8	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	067	16	SCREENING	-16	02NOV2010	10:00	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
			V1 (WEEK 0)	1	18NOV2010	9:00	LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V7 (WEEK 56)	111	08MAR2011	9:15	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL		< 20
							pH-VALUE				5.0 - 7.0
							PROTEIN		mg/L		< 150
							GLUCOSE		mmol/L		< 0.8
							KETONES		mmol/L		< 0.5
							BLOOD		/µL		< 5
							LEUKOCYTES		/µL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin.		Reference range
					Date	Time				High /Low	signi- ficant	
ACI-91	071	18	SCREENING	-20	20OCT2010	10:10	pH-VALUE	5.0			NCS	5.0 - 7.0
							PROTEIN	250	mg/L	HIGH	NCS	< 150
							GLUCOSE	17.0	mmol/L	HIGH	NCS	< 0.8
							KETONES	0.5	mmol/L	HIGH	NCS	< 0.5
							BLOOD	50	/µL	HIGH	NCS	< 5
			V1 (WEEK 0)	1	09NOV2010	10:45	LEUKOCYTES	25	/µL	HIGH	NCS	< 20
							pH-VALUE	8.0		HIGH	NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		NCS	< 0.5
			V3 (WEEK 12)	87	03FEB2011	10:12	BLOOD	10	/µL	HIGH	NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		NCS	< 20
							pH-VALUE	7.0			NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		NCS	< 0.8
			V4 (WEEK 24)	177	04MAY2011	9:30	KETONES	NEGATIVE	mmol/L		NCS	< 0.5
							BLOOD	25	/µL	HIGH	NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		NCS	< 20
							pH-VALUE	6.5			NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		NCS	< 0.5
							BLOOD	10	/µL	HIGH	NCS	< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin.		
					Date	Time				High /Low	signi- ficant	Reference range
ACI-91	071	18	V4 (WEEK 24)	177	04MAY2011	9:30	LEUKOCYTES	25	/µL	HIGH	NCS	< 20
			V5 (WEEK 36)	253	19JUL2011	11:03	pH-VALUE	7.0			NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		NCS	< 0.5
							BLOOD	10	/µL	HIGH	NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		NCS	< 20
			V6 (WEEK 52)	374	17NOV2011	13:00	pH-VALUE	8.0		HIGH	NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		NCS	< 0.5
							BLOOD	25	/µL	HIGH	NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		NCS	< 20
			V7 (WEEK 56)	392	05DEC2011	11:40	pH-VALUE	7.0			NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		NCS	< 0.5
							BLOOD	NEGATIVE	/µL		NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		NCS	< 20
	080	13	SCREENING	-10	08NOV2010	10:51	pH-VALUE	6.5				5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L			< 150
							GLUCOSE	NEGATIVE	mmol/L			< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	080	13	SCREENING	-10	08NOV2010	10:51	KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			UNSCHEDULED	42	29DEC2010	14:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							UNITRITE	NEGATIVE			negativ
							UROBILINOGEN	NORMAL	μmol/l		< 17
							BILIRUBIN	NEGATIVE	μmol/l		< 3.4
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	100	/μL	HIGH CS	< 20
			V1 (WEEK 0)	1	18NOV2010	12:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	1.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	84	09FEB2011	12:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	1.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	080	13	V3 (WEEK 12)	84	09FEB2011	12:20	LEUKOCYTES	NEGATIVE	/µL		< 20
			V6 (WEEK 52)	196	01JUN2011	13:00	pH-VALUE	8.0		HIGH NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	081	17	SCREENING	-10	04OCT2010	12:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
		V3 (WEEK 12)		89	10JAN2011	12:01	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
		V4 (WEEK 24)		175	06APR2011	11:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	081	17	V4 (WEEK 24)	175	06APR2011	11:50	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V6 (WEEK 52)		376	24OCT2011	12:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
		V7 (WEEK 56)		405	22NOV2011	12:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	083	17	SCREENING	-15	26OCT2010	12:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
			V1 (WEEK 0)	1	10NOV2010	10:15	LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	083	17	V1 (WEEK 0)	1	10NOV2010	10:15	PROTEIN	NEGATIVE	mg/L		< 150
			V4 (WEEK 24)	168	26APR2011	11:05	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
			V5 (WEEK 36)	258	25JUL2011	10:20	PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
			V6 (WEEK 52)	365	09NOV2011	12:00	LEUKOCYTES	100	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin.	Reference range
					Date	Time				High /Low	
ACI-91	083	17	V7 (WEEK 56)	392	06DEC2011	12:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	087	16	SCREENING	-20	09NOV2010	9:25	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		V3 (WEEK 12)	81	17FEB2011	10:00	pH-VALUE	7.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	
		V4 (WEEK 24)	169	16MAY2011	11:05	BLOOD	NEGATIVE	/μL		< 5	
						LEUKOCYTES	25	/μL	HIGH NCS	< 20	
						pH-VALUE	5.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	087	16	V4 (WEEK 24)	169	16MAY2011	11:05	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V5 (WEEK 36)	255	10AUG2011	11:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		5	V6 (WEEK 52)	365	28NOV2011	10:00	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V7 (WEEK 56)	395	28DEC2011	11:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	089	5	SCREENING	-28	20OCT2010	10:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	089	5	SCREENING	-28	20OCT2010	10:00	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
			V1 (WEEK 0)	1	16NOV2010	11:45	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
			V3 (WEEK 12)	84	08FEB2011	8:30	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
			V6 (WEEK 52)	364	14NOV2011	12:15	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	093	17	SCREENING	-3	29NOV2010	12:25	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V1 (WEEK 0)	1	02DEC2010	9:25	LEUKOCYTES	100	/μL	HIGH NCS	< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V3 (WEEK 12)	86	25FEB2011	11:15	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V4 (WEEK 24)	173	23MAY2011	12:31	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	093	17	V4 (WEEK 24)	173	23MAY2011	12:31	LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V6 (WEEK 52)	370	06DEC2011	11:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
		V7 (WEEK 56)					LEUKOCYTES	NEGATIVE	/µL		< 20
				392	28DEC2011	12:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
	097	12	SCREENING	-21	27OCT2010	8:50	LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
			V1 (WEEK 0)	1	17NOV2010	9:00	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
ACI-91	097	12	V1 (WEEK 0)	1	17NOV2010	9:00	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	85	09FEB2011	13:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
Placebo	001	1	SCREENING	-7	02APR2009	10:45	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	09APR2009	10:30	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	90	07JUL2009	8:55	pH-VALUE	7.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	001	1	V3 (WEEK 12)	90	07JUL2009	8:55	PROTEIN	NEGATIVE	mg/L		< 150
			V4 (WEEK 24)	162	17SEP2009	11:00	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	7.0			5.0 - 7.0
			V5 (WEEK 36)	246	10DEC2009	9:10	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	365	08APR2010	9:00	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High /Low signi- ficant	Reference range
					Date	Time					
Placebo	001	1	V7 (WEEK 56)	393	06MAY2010	13:20	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	003	1	SCREENING	-21	07MAY2009	10:10	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		V1 (WEEK 0)	1	28MAY2009	11:25	pH-VALUE	7.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	
		V3 (WEEK 12)	90	25AUG2009	11:50	pH-VALUE	7.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	003	1	V3 (WEEK 12)	90	25AUG2009	11:50	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V4 (WEEK 24)		169	12NOV2009	10:20	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	005	2	SCREENING	-16	19MAY2009	16:25	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V1 (WEEK 0)		1	04JUN2009	8:40	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		V3 (WEEK 12)		83	25AUG2009	8:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	005	2	V3 (WEEK 12)	83	25AUG2009	8:30	GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V4 (WEEK 24)	168	18NOV2009	10:05	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
			V6 (WEEK 52)	364	02JUN2010	9:15	KETONES	NEGATIVE	mmol/L		< 0.5
							BILIRUBIN	NEGATIVE	μmol/l		< 3.4
							BLOOD	NEGATIVE	/μL		< 5
							pH-VALUE	5.0			5.0 - 7.0
			V7 (WEEK 56)	400	08JUL2010	9:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
	009	1	SCREENING	-33	06AUG2009	11:40	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	009	1	SCREENING	-33	06AUG2009	11:40	GLUCOSE	56.7	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
			V1 (WEEK 0)	1	08SEP2009	9:10	PROTEIN	NEGATIVE	mg/L	HIGH NCS	< 150
							GLUCOSE	5.7	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	94	10DEC2009	9:40	pH-VALUE	5.0		HIGH NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V4 (WEEK 24)	178	04MAR2010	12:50	LEUKOCYTES	NEGATIVE	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	56.7	mmol/L		< 0.8
							KETONES	1.5	mmol/L		< 0.5
			V5 (WEEK 36)	246	11MAY2010	10:20	BLOOD	NEGATIVE	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range		
					Date	Time							
Placebo	009	1	V5 (WEEK 36)	246	11MAY2010	10:20	PROTEIN	NEGATIVE	mg/L		< 150		
							GLUCOSE	2.8	mmol/L	HIGH NCS	< 0.8		
							KETONES	NEGATIVE	mmol/L		< 0.5		
							BLOOD	NEGATIVE	/μL		< 5		
							LEUKOCYTES	25	/μL	HIGH NCS	< 20		
		V6 (WEEK 52)	361	03SEP2010	10:15	pH-VALUE	5.0			5.0 - 7.0			
						PROTEIN	NEGATIVE	mg/L		< 150			
						GLUCOSE	56.7	mmol/L	HIGH NCS	< 0.8			
						KETONES	0.5	mmol/L	HIGH NCS	< 0.5			
						BLOOD	NEGATIVE	/μL		< 5			
		V7 (WEEK 56)	389	01OCT2010	9:00	LEUKOCYTES	NEGATIVE	/μL		< 20			
						pH-VALUE	6.5			5.0 - 7.0			
						PROTEIN	NEGATIVE	mg/L		< 150			
						GLUCOSE	56.7	mmol/L	HIGH NCS	< 0.8			
						KETONES	0.5	mmol/L	HIGH NCS	< 0.5			
		011	1	SCREENING		-21	05NOV2009	13:10	BLOOD	NEGATIVE	/μL		< 5
									LEUKOCYTES	NEGATIVE	/μL		< 20
	pH-VALUE								6.0			5.0 - 7.0	
	PROTEIN								NEGATIVE	mg/L		< 150	
	GLUCOSE								NEGATIVE	mmol/L		< 0.8	

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	011	1	SCREENING V1 (WEEK 0)	-21 1	05NOV2009	13:10	LEUKOCYTES	25	/µL	HIGH NCS	< 20
					26NOV2009	10:25	pH-VALUE	5.0			5.0 - 7.0
			V3 (WEEK 12)	85	18FEB2010	9:00	PROTEIN	NEGATIVE	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
			V4 (WEEK 24)	162	06MAY2010	13:25	LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	5.0	mmol/L		< 0.5
			V5 (WEEK 36)	253	05AUG2010	12:10	BLOOD	NEGATIVE	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	011	1	V5 (WEEK 36)	253	05AUG2010	12:10	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V6 (WEEK 52)	366	26NOV2010	10:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	1.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
		4	V7 (WEEK 56)	397	27DEC2010	12:30	LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	750	mg/L	HIGH CS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	500	/µL	HIGH CS	< 20
	013	4	SCREENING	-30	17AUG2009	10:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		1	V1 (WEEK 0)	1	16SEP2009	12:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	013	4	V1 (WEEK 0)	1	16SEP2009	12:00	GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V3 (WEEK 12)	85	09DEC2009	11:45	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.5			5.0 - 7.0
			V4 (WEEK 24)	170	04MAR2010	11:30	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V5 (WEEK 36)	247	20MAY2010	10:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V6 (WEEK 52)	366	16SEP2010	11:15	BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
							pH-VALUE	8.0		HIGH NCS	5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	013	4	V6 (WEEK 52)	366	16SEP2010	11:15	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		4	V7 (WEEK 56)	400	20OCT2010	12:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	016	4	SCREENING	-28	01FEB2010	12:00	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
		4	V1 (WEEK 0)	1	01MAR2010	12:00	LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	016	4	V1 (WEEK 0)	1	01MAR2010	12:00	LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	80	19MAY2010	10:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V4 (WEEK 24)	162	09AUG2010	12:15	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	365	28FEB2011	11:00	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V7 (WEEK 56)	403	07APR2011	11:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	016	4	V7 (WEEK 56)	403	07APR2011	11:30	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	018	5	SCREENING	-20	03NOV2009	13:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	23NOV2009	13:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	86	16FEB2010	12:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V4 (WEEK 24)	170	11MAY2010	9:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	018	5	V4 (WEEK 24)	170	11MAY2010	9:00	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	366	23NOV2010	9:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V7 (WEEK 56)	387	14DEC2010	8:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	020	5	SCREENING	-26	27JAN2010	15:30	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	020	5	V1 (WEEK 0)	1	22FEB2010	13:10	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	5.7	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	024	4	SCREENING	-31	16JUL2010	12:00	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
		V1 (WEEK 0)		1	16AUG2010	11:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
		V3 (WEEK 12)		87	10NOV2010	10:25	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	024	4	V3 (WEEK 12)	87	10NOV2010	10:25	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V4 (WEEK 24)	171	02FEB2011	11:45	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V5 (WEEK 36)	246	18APR2011	10:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	358	08AUG2011	13:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V7 (WEEK 56)	393	12SEP2011	12:50	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	024	4	V7 (WEEK 56)	393	12SEP2011	12:50	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
	028	20	SCREENING	-8	18NOV2010	10:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V1 (WEEK 0)	1	26NOV2010	9:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V3 (WEEK 12)	89	22FEB2011	10:25	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH CS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH CS	< 0.5
							BLOOD	10	/µL	HIGH CS	< 5
							LEUKOCYTES	25	/µL	HIGH CS	< 20
			V4 (WEEK 24)	180	24MAY2011	10:15	pH-VALUE	5.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	028	20	V4 (WEEK 24)	180	24MAY2011	10:15	PROTEIN	250	mg/L	HIGH NCS	< 150
			V5 (WEEK 36)	273	25AUG2011	10:45	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
			V6 (WEEK 52)	364	24NOV2011	10:30	PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V7 (WEEK 56)	390	20DEC2011	10:16	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	029	8	SCREENING	-3	26JAN2010	10:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V1 (WEEK 0)	1	29JAN2010	15:00	LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V3 (WEEK 12)	82	20APR2010	11:00	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH CS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V4 (WEEK 24)	158	05JUL2010	10:30	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin.	Reference range
					Date	Time				High signi- /Low ficant	
Placebo	029	8	V4 (WEEK 24)	158	05JUL2010	10:30	LEUKOCYTES	100	/µL	HIGH CS	< 20
			V6 (WEEK 52)	369	01FEB2011	10:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
		8	V7 (WEEK 56)	391	23FEB2011	12:00	LEUKOCYTES	25	/µL	HIGH CS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH CS	< 5
	031	8	SCREENING	-14	06MAY2010	14:00	LEUKOCYTES	25	/µL	HIGH CS	< 20
							pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
	8	V1 (WEEK 0)	1	20MAY2010	11:00	LEUKOCYTES	NEGATIVE	/µL		< 20	
						pH-VALUE	5.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	031	8	V1 (WEEK 0)	1	20MAY2010	11:00	KETONES	0.5	mmol/L	HIGH NCS	< 0.5
			V3 (WEEK 12)	90	17AUG2010	11:40	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V4 (WEEK 24)	174	09NOV2010	11:40	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
			V6 (WEEK 52)	363	17MAY2011	13:00	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.0			5.0 - 7.0
			V7 (WEEK 56)	391	14JUN2011	10:20	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	031	8	V7 (WEEK 56)	391	14JUN2011	10:20	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	034	9	SCREENING	-22	24FEB2010	8:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
		V1 (WEEK 0)		1	18MAR2010	9:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
		V3 (WEEK 12)		83	08JUN2010	9:30	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	034	9	V4 (WEEK 24)	175	08SEP2010	8:35	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
			V5 (WEEK 36)	258	30NOV2010	8:10	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V7 (WEEK 56)	399	20APR2011	8:40	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
	041	12	SCREENING	-16	23SEP2009	11:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	041	12	SCREENING	-16	23SEP2009	11:00	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	09OCT2009	12:15	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	89	05JAN2010	13:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V4 (WEEK 24)	167	24MAR2010	9:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V5 (WEEK 36)	251	16JUN2010	9:20	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	041	12	V5 (WEEK 36)	251	16JUN2010	9:20	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	363	06OCT2010	8:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V7 (WEEK 56)	392	04NOV2010	8:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
	044	12	SCREENING	-28	04NOV2009	13:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		12	V1 (WEEK 0)	1	02DEC2009	9:45	pH-VALUE	8.0		HIGH NCS	5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	044	12	V1 (WEEK 0)	1	02DEC2009	9:45	PROTEIN	NEGATIVE	mg/L		< 150
			V3 (WEEK 12)	85	24FEB2010	9:30	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
			V4 (WEEK 24)	176	26MAY2010	13:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V5 (WEEK 36)	260	18AUG2010	8:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	500	/μL	HIGH NCS	< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	044	12	V6 (WEEK 52)	365	01DEC2010	11:50	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V7 (WEEK 56)	400	05JAN2011	13:10	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
	045	11	SCREENING	-14	07DEC2009	9:45	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							UROBILINOGEN	NORMAL	μmol/l		< 17
							BILIRUBIN	NEGATIVE	μmol/l		< 3.4
			V1 (WEEK 0)	1	21DEC2009	9:45	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	045	11	V1 (WEEK 0)	1	21DEC2009	9:45	GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V3 (WEEK 12)	85	15MAR2010	8:30	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
			V4 (WEEK 24)	169	07JUN2010	9:30	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V5 (WEEK 36)	260	06SEP2010	10:15	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V6 (WEEK 52)	360	15DEC2010	10:00	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	045	11	V6 (WEEK 52)	360	15DEC2010	10:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		V7 (WEEK 56)	393	17JAN2011	9:50	pH-VALUE	5.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	
						BLOOD	NEGATIVE	/μL		< 5	
	047	11	SCREENING	-21	12JUL2010	8:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
		V1 (WEEK 0)	1	02AUG2010	8:55	LEUKOCYTES	NEGATIVE	/μL		< 20	
						pH-VALUE	5.0			5.0 - 7.0	
						PROTEIN	NEGATIVE	mg/L		< 150	
						GLUCOSE	NEGATIVE	mmol/L		< 0.8	
						KETONES	NEGATIVE	mmol/L		< 0.5	
						BLOOD	NEGATIVE	/μL		< 5	

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	047	11	V1 (WEEK 0)	1	02AUG2010	8:55	LEUKOCYTES	NEGATIVE	/µL		< 20
			V3 (WEEK 12)	80	20OCT2010	11:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V4 (WEEK 24)	162	10JAN2011	10:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V6 (WEEK 52)	360	27JUL2011	7:40	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V7 (WEEK 56)	393	29AUG2011	8:35	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	047	11	V7 (WEEK 56)	393	29AUG2011	8:35	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	049	21	SCREENING	-51	06SEP2010	10:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V1 (WEEK 0)	1	27OCT2010	8:55	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	100	/μL	HIGH NCS	< 20
			V3 (WEEK 12)	84	18JAN2011	10:30	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V4 (WEEK 24)	168	12APR2011	11:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	049	21	V4 (WEEK 24)	168	12APR2011	11:00	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
		21	V5 (WEEK 36)	252	05JUL2011	10:00	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	750	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
	051	21	SCREENING	-52	06SEP2010	12:40	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
		21	V1 (WEEK 0)	1	28OCT2010	11:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
		21	V1 (WEEK 0)	1	28OCT2010	11:30	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	100	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
		21	V1 (WEEK 0)	1	28OCT2010	11:30	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	051	21	V3 (WEEK 12)	97	01FEB2011	11:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
			V4 (WEEK 24)	167	12APR2011	13:30	LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V5 (WEEK 36)	251	05JUL2011	13:42	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V6 (WEEK 52)	363	25OCT2011	10:30	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	051	21	V6 (WEEK 52)	363	25OCT2011	10:30	LEUKOCYTES	500	/µL	HIGH NCS	< 20
			V7 (WEEK 56)	391	22NOV2011	9:35	pH-VALUE	5.0			5.0 - 7.0
		5	SCREENING	-21	31MAR2010	10:00	PROTEIN	750	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L	NCS	< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	500	/µL	HIGH NCS	< 20
							pH-VALUE	6.5			5.0 - 7.0
	056	5	SCREENING	-21	31MAR2010	10:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
		1	V1 (WEEK 0)	1	21APR2010	9:15	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
		84	V3 (WEEK 12)	84	13JUL2010	11:15	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	9.0		HIGH NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	056	5	V3 (WEEK 12)	84	13JUL2010	11:15	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V4 (WEEK 24)	168	05OCT2010	9:15	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V6 (WEEK 52)	364	19APR2011	8:05	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
	058	1	SCREENING	-21	06DEC2010	10:00	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		1	V1 (WEEK 0)	1	27DEC2010	11:15	pH-VALUE	5.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	058	1	V1 (WEEK 0)	1	27DEC2010	11:15	PROTEIN	NEGATIVE	mg/L		< 150
			V3 (WEEK 12)	93	29MAR2011	11:10	GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	7.0			5.0 - 7.0
			V4 (WEEK 24)	166	10JUN2011	10:15	PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V5 (WEEK 36)	260	12SEP2011	10:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	058	1	V6 (WEEK 52)	345	06DEC2011	9:10	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH CS	< 5
			V7 (WEEK 56)	380	10JAN2012	10:25	LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
	059	1	SCREENING	-2	27DEC2010	13:00	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V1 (WEEK 0)	1	29DEC2010	10:05	KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	17.0	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	059	1	V1 (WEEK 0)	1	29DEC2010	10:05	BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V3 (WEEK 12)	93	31MAR2011	9:40	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V4 (WEEK 24)	161	07JUN2011	9:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	17.0	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V6 (WEEK 52)	345	08DEC2011	10:05	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	5.7	mmol/L	HIGH NCS	< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V7 (WEEK 56)	380	12JAN2012	11:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	059	1	V7 (WEEK 56)	380	12JAN2012	11:00	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	065	16	SCREENING	-20	10AUG2010	11:25	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	30AUG2010	9:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	+++	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	85	22NOV2010	11:15	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V4 (WEEK 24)	141	17JAN2011	12:00	pH-VALUE	7.0			5.0 - 7.0

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	065	16	V4 (WEEK 24)	141	17JAN2011	12:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	1.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	068	16	SCREENING	-27	26OCT2010	9:05	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V1 (WEEK 0)	1	22NOV2010	10:45	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V3 (WEEK 12)	81	14FEB2011	9:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH CS	< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	068	16	V3 (WEEK 12)	81	14FEB2011	9:30	LEUKOCYTES	100	/µL	HIGH CS	< 20
			V4 (WEEK 24)	163	03MAY2011	10:40	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
			V5 (WEEK 36)	262	10AUG2011	9:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
	069	23	SCREENING	-13	24NOV2010	12:30	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
			V1 (WEEK 0)	1	07DEC2010	12:10	GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	069	23	V1 (WEEK 0)	1	07DEC2010	12:10	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	23	/µL		< 25
			V3 (WEEK 12)	93	09MAR2011	12:20	BLOOD	10	/µL	HIGH NCS	< 5
							LEUKOCYTES	1	/µL		< 20
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V4 (WEEK 24)	164	19MAY2011	9:50	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V5 (WEEK 36)	261	24AUG2011	11:10	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	25	/µL	HIGH NCS	< 5
							LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	069	23	V6 (WEEK 52)	373	14DEC2011	9:20	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V7 (WEEK 56)	401	11JAN2012	10:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
	072	18	SCREENING	-20	01DEC2010	12:45	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	21DEC2010	12:25	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- Reference /Low ficant range	
					Date	Time					
Placebo	072	18	V1 (WEEK 0)	1	21DEC2010	12:25	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	85	15MAR2011	11:10	pH-VALUE	7.0		NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L	NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L	NCS	< 0.8
							KETONES	NEGATIVE	mmol/L	NCS	< 0.5
							BLOOD	NEGATIVE	/μL	NCS	< 5
							LEUKOCYTES	(+)	/μL	NCS	< 20
			V4 (WEEK 24)	169	07JUN2011	10:07	pH-VALUE	7.0		NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L	NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L	NCS	< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	NEGATIVE	/μL	NCS	< 20
			V5 (WEEK 36)	262	08SEP2011	12:10	pH-VALUE	7.0		NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L	NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L	NCS	< 0.8
							KETONES	NEGATIVE	mmol/L	NCS	< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V6 (WEEK 52)	360	15DEC2011	10:10	pH-VALUE	8.0		HIGH NCS	5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L	NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L	NCS	< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High /Low signi- ficant	Reference range				
					Date	Time									
Placebo	072	18	V6 (WEEK 52)	360	15DEC2011	10:10	KETONES	NEGATIVE	mmol/L	NCS	< 0.5				
							BLOOD	NEGATIVE	/μL	NCS	< 5				
							LEUKOCYTES	NEGATIVE	/μL	NCS	< 20				
			V7 (WEEK 56)	393	17JAN2012	10:24	pH-VALUE	7.0	NCS	5.0 – 7.0					
							PROTEIN	NEGATIVE	mg/L	NCS	< 150				
							GLUCOSE	NEGATIVE	mmol/L	NCS	< 0.8				
							KETONES	NEGATIVE	mmol/L	NCS	< 0.5				
							BLOOD	NEGATIVE	/μL	NCS	< 5				
							LEUKOCYTES	NEGATIVE	/μL	NCS	< 20				
	079	13	SCREENING	-18	19JUL2010	15:03	pH-VALUE	5.0				5.0 – 7.0			
							PROTEIN	NEGATIVE	mg/L		< 150				
							GLUCOSE	NEGATIVE	mmol/L		< 0.8				
							KETONES	NEGATIVE	mmol/L		< 0.5				
							BLOOD	10	/μL	HIGH NCS	< 5				
							LEUKOCYTES	500	/μL	HIGH NCS	< 20				
							V1 (WEEK 0)	1	06AUG2010	9:55	pH-VALUE	7.0			5.0 – 7.0
											PROTEIN	NEGATIVE	mg/L		< 150
											GLUCOSE	NEGATIVE	mmol/L		< 0.8
											KETONES	NEGATIVE	mmol/L		< 0.5
											BLOOD	NEGATIVE	/μL		< 5
		V3 (WEEK 12)	96	09NOV2010	12:10	LEUKOCYTES	25	/μL	HIGH NCS	< 20					
pH-VALUE	5.0							5.0 – 7.0							

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	079	13	V3 (WEEK 12)	96	09NOV2010	12:10	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V4 (WEEK 24)	175	27JAN2011	15:10	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
			V6 (WEEK 52)	320	21JUN2011	11:20	LEUKOCYTES	100	/μL	HIGH NCS	< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V7 (WEEK 56)	348	19JUL2011	14:40	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	082	17	SCREENING	-8	06OCT2010	11:23	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V3 (WEEK 12)	84	05JAN2011	12:45	LEUKOCYTES	25	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V4 (WEEK 24)	175	06APR2011	9:31	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
			V6 (WEEK 52)	364	12OCT2011	12:20	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	082	17	V6 (WEEK 52)	364	12OCT2011	12:20	LEUKOCYTES	25	/µL	HIGH NCS	< 20
			V7 (WEEK 56)	407	24NOV2011	10:00	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
	084	17	SCREENING	-9	08NOV2010	9:50	LEUKOCYTES	25	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/µL		< 5
			V1 (WEEK 0)	1	17NOV2010	11:45	LEUKOCYTES	100	/µL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
			V3 (WEEK 12)	84	08FEB2011	12:05	LEUKOCYTES	NEGATIVE	/µL		< 20
							pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	084	17	V3 (WEEK 12)	84	08FEB2011	12:05	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
		V4 (WEEK 24)		175	10MAY2011	12:03	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	250	mg/L	HIGH NCS	< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
		V6 (WEEK 52)		371	22NOV2011	12:30	KETONES	0.5	mmol/L	HIGH NCS	< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
		V7 (WEEK 56)		394	15DEC2011	10:30	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
	086	21	SCREENING	-24	04OCT2010	11:00	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	10	/μL	HIGH NCS	< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	086	21	SCREENING	-24	04OCT2010	11:00	PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	28OCT2010	14:05	pH-VALUE	6.5			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V3 (WEEK 12)	83	18JAN2011	11:30	LEUKOCYTES	100	/μL	HIGH NCS	< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V4 (WEEK 24)	167	12APR2011	11:55	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	086	21	V5 (WEEK 36)	251	05JUL2011	11:57	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
			V6 (WEEK 52)	363	25OCT2011	13:20	LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
			V7 (WEEK 56)	391	22NOV2011	11:55	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
							pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
	088	16	SCREENING	-9	30NOV2010	10:15	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	088	16	SCREENING	-9	30NOV2010	10:15	BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V1 (WEEK 0)	1	09DEC2010	9:20	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	NEGATIVE	/μL		< 20
			V3 (WEEK 12)	83	01MAR2011	11:00	pH-VALUE	6.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V4 (WEEK 24)	162	19MAY2011	9:45	pH-VALUE	7.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8
							KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/μL		< 5
							LEUKOCYTES	25	/μL	HIGH NCS	< 20
			V5 (WEEK 36)	264	29AUG2011	9:50	pH-VALUE	5.0			5.0 - 7.0
							PROTEIN	NEGATIVE	mg/L		< 150
							GLUCOSE	NEGATIVE	mmol/L		< 0.8

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Listing 16.2.8.4: Urinalysis

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Treat- ment	Random No.	Site ID	Visit	Actual day	Urine sampling		Parameter	Result	Unit	Clin. High signi- /Low ficant	Reference range
					Date	Time					
Placebo	088	16	V5 (WEEK 36)	264	29AUG2011	9:50	KETONES	NEGATIVE	mmol/L		< 0.5
							BLOOD	NEGATIVE	/µL		< 5
							LEUKOCYTES	NEGATIVE	/µL		< 20

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	002	1	SCREENING	-7	16APR2009	9:50	121	76	75	123	84	80	37.1	
			V1 (WEEK 0)	1	23APR2009	8:45	120	82	64	117	77	66	36.9	65
			V2 (WEEK 4)	28	20MAY2009	9:35	108	70	62	122	81	63	36.5	
			V3 (WEEK 12)	85	16JUL2009	8:30	120	76	69	118	74	80	36.9	
			V4 (WEEK 24)	169	08OCT2009	10:28	117	78	60	130	82	61	36.8	
			V5 (WEEK 36)	258	05JAN2010	9:16	113	76	66	120	76	71	36.7	67
			V6 (WEEK 52)	365	22APR2010	9:45	110	71	61	104	78	66	36.8	66
			V7 (WEEK 56)	393	20MAY2010	9:30	122	74	73	128	78	89	36.9	67
	004	1	SCREENING	-29	17JUN2009	11:35	145	84	66	153	83	67	36.3	
			V1 (WEEK 0)	1	16JUL2009	10:10	134	74	73	127	75	81	36.6	60
			V2 (WEEK 4)	28	12AUG2009	9:30	122	71	75	120	80	80	36.3	
			V3 (WEEK 12)	92	15OCT2009	14:55	129	75	70	134	75	76	36.1	60
	006	2	SCREENING	-32	25JAN2010	9:00	150	80	72	145	75	72	35.9	
			V1 (WEEK 0)	1	26FEB2010	9:00	140	85	64	160	95	68	36.1	75
			V2 (WEEK 4)	29	26MAR2010	9:40	135	90	64	140	85	76	36.4	
			V3 (WEEK 12)	85	21MAY2010	9:15	155	90	64	175	95	64	35.2	76
			V4 (WEEK 24)	169	13AUG2010	9:00	140	80	72	155	85	72	36.1	77
			V5 (WEEK 36)	252	04NOV2010	8:45	140	85	68	145	85	72	36.8	77
			V6 (WEEK 52)	364	24FEB2011	8:30	147	87	71	138	93	81	36.4	78
			V7 (WEEK 56)	390	22MAR2011	8:45	157	87	76	145	87	85	36.2	77

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	010	1	SCREENING	-26	25JUN2009	9:30	127	72	54	141	88	73	36.4	71
			V1 (WEEK 0)	1	21JUL2009	11:00	140	78	57	152	80	62	36.4	
			V2 (WEEK 4)	31	20AUG2009	10:45	119	73	61	133	78	63	36.8	
			V3 (WEEK 12)	85	13OCT2009	10:35	131	81	62	126	81	69	36.2	
	012	1	SCREENING	-32	17JUN2010	11:00	128	66	52	137	69	57	36.4	67
			V1 (WEEK 0)	1	19JUL2010	9:40	140	69	55	136	68	64	36.3	64
			V2 (WEEK 4)	25	12AUG2010	9:20	161	67	55	144	74	59	36.1	67
			V3 (WEEK 12)	88	14OCT2010	9:35	151	69	47	159	74	51	36.2	63
			V4 (WEEK 24)	176	10JAN2011	10:45	163	63	44	177	68	47	36.0	68
			V5 (WEEK 36)	257	01APR2011	9:20	162	79	50	158	80	57	36.4	65
			V6 (WEEK 52)	361	14JUL2011	10:20	166	69	44	182	73	49	36.0	64
			V7 (WEEK 56)	396	18AUG2011	11:40	131	70	52	162	74	57	36.8	66
	014	4	SCREENING	-26	07OCT2009	14:00	110	75	65	115	80	68	36.3	93
			V1 (WEEK 0)	1	02NOV2009	12:00	120	80	56	125	88	60	36.6	
			V2 (WEEK 4)	32	03DEC2009	10:15	110	70	66	120	80	68	37.0	
			V3 (WEEK 12)	85	25JAN2010	11:38	120	80	60	125	85	63	36.7	
			V4 (WEEK 24)	172	22APR2010	10:38	115	75	66	110	70	68	36.6	
			V5 (WEEK 36)	256	15JUL2010	12:00	120	80	54	105	70	60	36.1	
			V6 (WEEK 52)	361	28OCT2010	13:00	120	80	55	110	75	60	36.5	
			V7 (WEEK 56)	396	02DEC2010	13:30	120	80	60	115	75	64	36.5	

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Listing 16.2.9.1.1: Vital signs / body temperature

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	015	4	SCREENING	-32	21JAN2010	12:40	130	80	53	125	70	55	37.2	64
			V1 (WEEK 0)	1	22FEB2010	12:00	120	80	49	115	80	50	36.8	66
			V2 (WEEK 4)	29	22MAR2010	10:15	115	70	60	120	75	62	36.8	66
			V3 (WEEK 12)	85	17MAY2010	11:40	155	85	58	155	90	68	37.0	66
			V4 (WEEK 24)	162	02AUG2010	11:40	140	80	56	140	80	68	37.0	65
			V5 (WEEK 36)	248	27OCT2010	12:30	140	85	68	130	80	72	36.7	67
			V6 (WEEK 52)	365	21FEB2011	14:00	130	80	66	130	80	60	36.6	68
			V7 (WEEK 56)	394	22MAR2011	12:00	138	80	58	140	80	60	36.3	68
	017	5	SCREENING	-22	14JUL2009	9:40	160	95	98				36.4	85
			V1 (WEEK 0)	1	05AUG2009	10:40	130	90	81	140	90	84	36.5	82
			UNSCHEDULED	9	13AUG2009	10:30	120	80	96					
			V2 (WEEK 4)	29	02SEP2009	10:00	130	80	68	140	80	64	36.2	
			V3 (WEEK 12)	85	28OCT2009	8:50	145	80	78	140	80	76	36.0	80
			V4 (WEEK 24)	169	20JAN2010	9:00	140	90	81	130	80	80	36.6	82
			V5 (WEEK 36)	252	13APR2010	11:00	160	90	88	150	85	84	36.4	84
			V6 (WEEK 52)	364	03AUG2010	9:10	130	70	84	140	80	88	35.9	86
			V7 (WEEK 56)	392	31AUG2010	9:00	160	100	84	170	100	80	36.4	86
	019	5	SCREENING	-21	18NOV2009	13:15	110	70	58	100	60	62	36.7	96
			V1 (WEEK 0)	1	09DEC2009	9:00	120	80	64	110	70	60	35.9	97
			V2 (WEEK 4)	29	06JAN2010	9:10	110	70	68	110	65	72	36.6	97

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	019	5	V3 (WEEK 12)	85	03MAR2010	8:50	110	70	64	110	70	60	36.1	98
			V4 (WEEK 24)	168	25MAY2010	9:00	100	60	72	95	60	68	36.0	102
			V5 (WEEK 36)	259	24AUG2010	11:45	100	60	68	95	60	72	36.2	95
			V6 (WEEK 52)	364	07DEC2010	9:00	140	90	76	120	80	80	36.4	96
			V7 (WEEK 56)	399	11JAN2011	9:00	140	80	72	150	80	72	36.4	96
	023	4	SCREENING	-19	01JUL2010	13:30	110	70	56	115	75	60	36.7	82
			V1 (WEEK 0)	1	20JUL2010	12:15	110	80	60	130	80	62	37.0	82
			V2 (WEEK 4)	24	12AUG2010	11:30	115	80	70	120	80	68	37.1	83
			V3 (WEEK 12)	86	13OCT2010	12:15	125	85	55	120	75	54	37.2	83
			V4 (WEEK 24)	177	12JAN2011	13:20	130	80	70	120	80	72	37.1	85
			V5 (WEEK 36)	245	21MAR2011	12:30	150	90	74	160	100	76	36.9	84
			V6 (WEEK 52)	364	18JUL2011	12:30	135	90	76	130	90	78	37.2	82
			V7 (WEEK 56)	388	11AUG2011	13:00	153	89	73	135	83	77	36.3	82
	027	20	SCREENING	-21	30SEP2010	10:30	140	85	64	125	85	64	36.3	51
			V1 (WEEK 0)	1	21OCT2010	12:00	140	90	81	130	85	79	36.2	51
			V2 (WEEK 4)	29	18NOV2010	12:40	130	80	60	120	95	76	35.5	61
			V3 (WEEK 12)	92	20JAN2011	11:00	118	83	71	115	70	75	36.9	60
			V4 (WEEK 24)	174	12APR2011	13:30	120	80	70	120	75	72	36.3	59
			V5 (WEEK 36)	259	06JUL2011	9:50	140	90	84	130	90	80	36.0	60
			V6 (WEEK 52)	370	25OCT2011	9:40	160	90	74	160	95	76	36.0	58

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Listing 16.2.9.1.1: Vital signs / body temperature

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	027	20	V7 (WEEK 56)	407	01DEC2011	10:08	120	75	64	115	80	73	35.0	58
	030	8	SCREENING	-7	18MAR2010	13:25	130	65	50	140	68	52	36.7	62
			V1 (WEEK 0)	1	25MAR2010	12:10	160	75	50	130	70	48	36.5	61
			V2 (WEEK 4)	28	21APR2010	11:52	135	70	72	128	70	84	37.5	61
			V3 (WEEK 12)	85	17JUN2010	12:55	130	65	60	140	85	58	36.4	61
			V4 (WEEK 24)	163	03SEP2010	12:51	150	75	58	135	65	60	37.6	61
			V5 (WEEK 36)	253	02DEC2010	12:40	160	80	58	160	75	56	37.5	61
			V6 (WEEK 52)	355	14MAR2011									63
			V7 (WEEK 56)	383	11APR2011	11:10	120	65	94	110	65	90	36.7	62
	032	8	SCREENING	-10	08NOV2010	11:10	125	65	56	120	70	52	36.9	58
			V1 (WEEK 0)	1	18NOV2010	13:00	130	65	58	125	65	58	37.2	58
			V2 (WEEK 4)	30	17DEC2010	10:20	115	70	58	110	60	60	37.4	58
			V3 (WEEK 12)	82	07FEB2011	12:10	120	70	54	125	70	60	36.7	59
	033	9	SCREENING	-7	28OCT2009	8:00	151	83	66	120	98	71	36.5	88
			V1 (WEEK 0)	1	04NOV2009	8:00	136	86	70	137	86	74	36.4	89
			V2 (WEEK 4)	29	02DEC2009	9:00	166	105	78	140	104	82	36.1	89
			V3 (WEEK 12)	78	20JAN2010	9:00	155	111	85	138	102	82	36.0	91
			V4 (WEEK 24)	169	21APR2010	9:45	123	81	77	119	82	78	35.8	89
			V5 (WEEK 36)	261	22JUL2010	9:00	145	110	76	136	91	80	36.0	90

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Listing 16.2.9.1.1: Vital signs / body temperature

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	033	9	V6 (WEEK 52)	372	10NOV2010	8:37	140	90	84	150	90	88	35.8	89
			V7 (WEEK 56)	398	06DEC2010	8:50	154	97	83	130	108	78	35.4	90
	042	12	SCREENING	-29	16DEC2009	9:35	160	80	80	155	80	76	37.1	
			V1 (WEEK 0)	1	14JAN2010	9:30	170	100	64	180	100	84	37.0	58
			V2 (WEEK 4)	29	11FEB2010	9:50	130	80	80	160	90	84	36.8	60
			V3 (WEEK 12)	126	19MAY2010	8:40	140	80	80	160	80	80	37.0	59
			V4 (WEEK 24)	168	30JUN2010	8:15	130	60	68	140	70	80	36.8	61
			V5 (WEEK 36)	252	22SEP2010	8:35	130	60	60	140	70	64	36.5	61
			V6 (WEEK 52)	364	12JAN2011	8:45	140	80	64	150	90	64	36.9	59
			V7 (WEEK 56)	391	08FEB2011	8:30	120	80	60	150	80	80	36.8	59
	043	12	SCREENING	-28	21OCT2009	9:30	130	80	84	130	80	84	37.4	88
			V1 (WEEK 0)	1	18NOV2009	9:40	130	80	84	130	80	84	36.2	86
			V2 (WEEK 4)	29	16DEC2009	10:30	120	80	80	140	80	84	37.0	
			V3 (WEEK 12)	85	10FEB2010	11:00	120	80	80	130	80	80	37.2	82
			V4 (WEEK 24)	176	12MAY2010	9:00	100	70	68	110	70	70	37.1	73
			V6 (WEEK 52)	267	11AUG2010	10:30	100	70	96					
	046	11	SCREENING	-28	14DEC2009	9:30	140	95	108	145	95	112	35.8	54
			V1 (WEEK 0)	1	11JAN2010	10:08	120	70	76	130	75	80	35.4	55
			V2 (WEEK 4)	29	08FEB2010	9:05	120	70	84	130	80	92	36.5	52

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Listing 16.2.9.1.1: Vital signs / body temperature

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	046	11	V3 (WEEK 12)	87	07APR2010	9:30	130	80	96	150	80	100	36.2	52
			V4 (WEEK 24)	178	07JUL2010	11:40	165	95	88	175	95	88	36.5	54
			V5 (WEEK 36)	255	22SEP2010	11:48	140	80	96	145	85	96	36.1	56
			V6 (WEEK 52)	367	12JAN2011	12:00	145	85	88	145	85	92	35.6	60
			V7 (WEEK 56)	393	07FEB2011	8:20	110	75	88	110	80	92	36.3	60
	048	11	SCREENING	-5	17NOV2010	11:15	130	80	72	140	90	76	36.4	84
			V1 (WEEK 0)	1	22NOV2010	10:45	160	90	76	165	95	80	36.5	84
			V2 (WEEK 4)	30	21DEC2010	14:05	135	80	72	140	80	76	35.7	84
			V3 (WEEK 12)	86	15FEB2011	11:05	130	80	76	130	80	76	36.3	84
			V4 (WEEK 24)	176	16MAY2011	11:32	135	80	76	135	85	80	36.8	83
			V5 (WEEK 36)	247	26JUL2011	10:45	130	90	76	135	90	76	36.3	83
			V6 (WEEK 52)	360	16NOV2011	12:00	120	80	76	125	75	76	36.2	83
			V7 (WEEK 56)	395	21DEC2011	11:25	120	80	88	140	85	80	36.2	83
	050	21	SCREENING	-51	06SEP2010	15:57	129	79	99	144	75	107	35.0	50
			V1 (WEEK 0)	1	27OCT2010	13:45	150	91	62	120	90	75	34.7	56
			V2 (WEEK 4)	27	22NOV2010	9:37	158	102	57	119	83	84	36.7	52
			V3 (WEEK 12)	83	17JAN2011	12:00	158	104	67	122	94	79	36.6	54
			V4 (WEEK 24)	167	11APR2011	11:40	139	101	68	122	99	79	34.9	52
			UNSCHEDULED	211	25MAY2011	9:15	138	87	64					
			V5 (WEEK 36)	251	04JUL2011	11:45	145	105	60	122	90	75	36.7	53

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	050	21	V6 (WEEK 52)	363	24OCT2011	8:51	148	94	66	141	97	74	36.2	52
			V7 (WEEK 56)	391	21NOV2011	8:30	117	78	63	100	78	77	36.1	53
	052	21	SCREENING	-52	06SEP2010	14:40	145	78	70	150	95	83	35.9	71
			V1 (WEEK 0)	1	28OCT2010	9:14	158	106	59	176	125	82	35.0	72
			V2 (WEEK 4)	27	23NOV2010	10:08	148	104	67	156	111	83	36.2	72
			V3 (WEEK 12)	82	17JAN2011	11:29	186	118	65	174	135	59	36.3	74
			V4 (WEEK 24)	166	11APR2011	11:23	194	125	63	182	123	82	35.0	75
			V5 (WEEK 36)	250	04JUL2011	10:00	174	126	60	165	122	74	35.7	75
			V6 (WEEK 52)	362	24OCT2011	12:25	164	112	67	164	119	80	36.4	76
			V7 (WEEK 56)	390	21NOV2011	9:57	164	115	70	161	122	85	36.4	77
	055	5	SCREENING	-21	08MAR2010	11:30	130	90	52	120	80	52	36.0	52
			V1 (WEEK 0)	1	29MAR2010	9:20	135	90	64	130	85	60	36.4	73
			V6 (WEEK 52)	30	27APR2010	9:30	130	80	68	125	80	64	36.4	74
	057	1	SCREENING	-21	29JUL2010	10:15	133	90	61	130	80	66	36.4	91
			V1 (WEEK 0)	1	19AUG2010	11:00	134	77	57	137	77	64	36.6	89
			V2 (WEEK 4)	33	20SEP2010	9:45	134	75	66	131	70	72	36.6	92
			V3 (WEEK 12)	82	08NOV2010	10:15	147	81	55	133	68	69	36.4	91
			V4 (WEEK 24)	170	04FEB2011	9:30	118	81	60	122	72	71	36.4	92

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	066	16	SCREENING	-31	09AUG2010	10:35	130	80	68	135	85	72	36.5	80
			V1 (WEEK 0)	1	09SEP2010	9:10	130	74	64	135	70	68	36.2	80
			V2 (WEEK 4)	28	06OCT2010	9:45	153	77	72	155	75	68	36.3	83
			V3 (WEEK 12)	83	30NOV2010	9:05	155	75	78	150	72	72	36.5	84
	067	16	SCREENING	-16	02NOV2010	10:15	140	60	80	145	60	76	36.2	77
			V1 (WEEK 0)	1	18NOV2010	8:25	140	90	72	140	95	68	36.4	72
			V2 (WEEK 4)	29	16DEC2010	10:00	140	80	72	135	80	68	36.4	77
			V6 (WEEK 52)	69	25JAN2011	11:00	120	80	72	125	85	65	36.3	77
			V7 (WEEK 56)	111	08MAR2011	9:00	140	90	74	138	90	68	36.2	76
	071	18	SCREENING	-20	20OCT2010	9:55	140	82	52	121	75	56	36.0	59
			V1 (WEEK 0)	1	09NOV2010	11:39	141	76	54	141	88	64	36.4	59
			V2 (WEEK 4)	24	02DEC2010	10:09	154	77	59	164	93	66	37.0	60
			V3 (WEEK 12)	87	03FEB2011	9:57	151	88	53	165	85	64	36.0	57
			UNSCHEDULED	99	15FEB2011	10:04	148	74	60	131	85	68	36.8	56
			V4 (WEEK 24)	177	04MAY2011	10:29	178	92	49	156	89	63	36.4	57
			V5 (WEEK 36)	253	19JUL2011	9:30	162	92	65	159	94	67	36.7	57
			V6 (WEEK 52)	374	17NOV2011	11:45	182	90	67	170	98	71	36.6	53
			V7 (WEEK 56)	392	05DEC2011	12:10	172	90	64	165	92	68	36.9	55
	080	13	SCREENING	-10	08NOV2010	10:36	139	75	77	138	86	80	36.1	68

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	080	13	V1 (WEEK 0)	1	18NOV2010	13:00	149	88	75	151	93	81	35.5	69
			V2 (WEEK 4)	26	13DEC2010	10:05	137	75	87	130	70	90	36.6	71
			UNSCHEDULED	42	29DEC2010	14:50	126	69	78	164	80	92	36.4	
			V3 (WEEK 12)	84	09FEB2011	13:26	141	94	84	143	95	78	36.7	67
			V6 (WEEK 52)	196	01JUN2011	12:55	121	68	55	132	72	68	36.0	71
	081	17	SCREENING	-10	04OCT2010	11:50	125	80	72	130	90	78	36.7	62
			V1 (WEEK 0)	1	14OCT2010	9:45	123	80	70	130	85	75	36.7	62
			V2 (WEEK 4)	33	15NOV2010	10:15	122	81	69	130	90	72	36.7	62
			V3 (WEEK 12)	89	10JAN2011	11:30	123	75	65	130	80	70	36.7	62
			V4 (WEEK 24)	175	06APR2011	9:15	120	75	69	130	81	78	36.7	67
			V5 (WEEK 36)	250	20JUN2011	10:50	122	70	65	131	88	72	36.7	62
			V6 (WEEK 52)	376	24OCT2011	10:20	120	75	69	131	83	75	36.7	62
			V7 (WEEK 56)	405	22NOV2011	10:30	121	80	69	130	90	72	36.7	62
	083	17	SCREENING	-15	26OCT2010	11:10	125	82	72	131	78	70	36.7	60
			V1 (WEEK 0)	1	10NOV2010	10:20	126	83	71	132	90	78	36.8	60
			V2 (WEEK 4)	29	08DEC2010	10:12	123	75	68	131	85	75	36.7	60
			V3 (WEEK 12)	85	02FEB2011	9:50	128	75	69	134	80	75	36.7	60
			V4 (WEEK 24)	168	26APR2011	9:45	125	80	68	132	90	72	36.8	60
			V5 (WEEK 36)	258	25JUL2011	11:00	128	77	70	135	82	75	36.7	60
			V6 (WEEK 52)	365	09NOV2011	10:10	129	81	78	133	90	80	36.7	60

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	083	17	V7 (WEEK 56)	392	06DEC2011	10:05	125	75	69	130	80	75	36.7	61
	087	16	SCREENING	-20	09NOV2010	9:15	140	60	60	140	65	64	36.4	64
			V1 (WEEK 0)	1	29NOV2010	9:40	145	75	78	140	72	68	36.5	64
			V2 (WEEK 4)	30	28DEC2010	11:45	145	80	68	145	85	72	36.4	58
			V3 (WEEK 12)	81	17FEB2011	9:30	135	80	64	145	72	68	35.3	61
			V4 (WEEK 24)	169	16MAY2011	10:50	135	80	70	140	80	74	36.1	62
			V5 (WEEK 36)	255	10AUG2011	10:15	128	76	64	140	75	68	35.5	63
			V6 (WEEK 52)	365	28NOV2011	10:10	125	75	76	128	72	80	36.0	66
			V7 (WEEK 56)	395	28DEC2011	11:30	175	82	68	172	80	72	36.0	67
	089	5	SCREENING	-28	19OCT2010	12:00	130	90	56	120	80	60	36.4	69
			V1 (WEEK 0)	1	16NOV2010	9:00	110	70	60	105	70	64	36.4	72
			V2 (WEEK 4)	29	14DEC2010	9:30	130	80	64	130	70	68	36.3	70
			V3 (WEEK 12)	84	07FEB2011	11:30	110	80	60	90	60	60	36.4	71
			V4 (WEEK 24)	168	02MAY2011	10:20	120	80	60	110	80	60	36.2	71
			V5 (WEEK 36)	252	25JUL2011	11:50	113	67	63	120	60	65	35.9	69
			V6 (WEEK 52)	364	14NOV2011	14:11	160	90	54	155	80	54	36.1	69
			V7 (WEEK 56)	394	14DEC2011	12:45	116	80	63	122	90	64	36.4	70
	093	17	SCREENING	-3	29NOV2010	12:20	115	70	62	128	81	72	36.7	73
			V1 (WEEK 0)	1	02DEC2010	9:10	125	70	65	130	81	70	36.7	65

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
ACI-91	093	17	V2 (WEEK 4)	35	05JAN2011	9:30	120	80	65	130	92	73	36.7	65
			V3 (WEEK 12)	86	25FEB2011	12:50	118	66	67	118	70	72	36.7	64
			V4 (WEEK 24)	173	23MAY2011	11:32	122	72	69	130	79	71	36.7	64
			V5 (WEEK 36)	258	16AUG2011	10:20	125	71	63	131	88	75	36.7	63
			V6 (WEEK 52)	370	06DEC2011	10:20	120	80	68	132	89	75	36.7	62
			V7 (WEEK 56)	392	28DEC2011	9:50	120	80	67	130	90	72	36.8	63
	097	12	SCREENING	-21	27OCT2010	8:20	160	80	72	170	80	72	36.3	89
			V1 (WEEK 0)	1	17NOV2010	8:50	160	80	80	170	90	84	37.1	89
			V2 (WEEK 4)	28	14DEC2010	9:30	140	80	60	150	90	84	37.1	91
			V3 (WEEK 12)	85	09FEB2011	8:30	160	90	80	170	100	84	36.7	91
Placebo	001	1	SCREENING	-7	02APR2009	10:35	180	110	77	190	114	78	36.7	
			V1 (WEEK 0)	1	09APR2009	10:35	162	105	74	165	100	75	36.8	71
			V2 (WEEK 4)	29	07MAY2009	9:30	153	90	80	187	103	87	36.7	
			V3 (WEEK 12)	90	07JUL2009	9:00	155	90	73	149	100	73	36.2	
			V4 (WEEK 24)	162	17SEP2009	9:10	147	97	71	140	107	76	36.7	
			V5 (WEEK 36)	246	10DEC2009	9:05	163	98	67	154	102	72	36.3	74
			V6 (WEEK 52)	365	08APR2010	9:15	158	94	62	155	94	63	37.0	77
	003	1	V7 (WEEK 56)	393	06MAY2010	13:20	142	88	61	143	102	70	36.3	77
			SCREENING	-21	07MAY2009	10:20	155	85	63	162	91	66	36.9	

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	003	1	V1 (WEEK 0)	1	28MAY2009	9:05	188	106	77	180	107	73	36.8	65
			V2 (WEEK 4)	28	24JUN2009	9:30	125	85	64	140	90	72	36.7	
			V3 (WEEK 12)	90	25AUG2009	11:15	140	90	64	140	90	68	36.9	
			V4 (WEEK 24)	169	12NOV2009	10:05	160	90	64	155	90	60	36.6	65
	005	2	SCREENING	-16	19MAY2009	14:15	140	80	60	135	75	72	36.2	
			V1 (WEEK 0)	1	04JUN2009	12:15	165	90	56	160	85	52	36.9	74
			V2 (WEEK 4)	27	30JUN2009	9:35	95	55	64	125	65	68	36.1	
			V3 (WEEK 12)	83	25AUG2009	8:48	125	70	60	135	70	60		
			V4 (WEEK 24)	168	18NOV2009	9:20	115	65	60	125	75	60	35.8	
			V5 (WEEK 36)	258	16FEB2010	9:00	120	70	64	140	80	64	36.1	77
			V6 (WEEK 52)	364	02JUN2010	9:15	120	70	64	130	80	72	35.4	76
			V7 (WEEK 56)	400	08JUL2010	8:45	100	60	68	115	70	68	35.9	76
	009	1	SCREENING	-33	06AUG2009	13:00	157	79	70	157	85	72	36.6	67
			V1 (WEEK 0)	1	08SEP2009	9:30	124	73	75	132	73	81	36.9	66
			V2 (WEEK 4)	30	07OCT2009	10:15	131	78	72	126	79	75	36.1	
			V3 (WEEK 12)	94	10DEC2009	9:45	159	80	72	150	82	81	36.2	67
			V4 (WEEK 24)	178	04MAR2010	13:00	138	77	63	142	79	72	36.7	63
			V5 (WEEK 36)	246	11MAY2010	9:15	157	84	70	151	86	70	36.1	68
			V6 (WEEK 52)	361	03SEP2010	10:50	129	76	66	138	77	76	36.9	68
			V7 (WEEK 56)	389	01OCT2010	9:10	133	78	76	138	80	79	36.6	68

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	011	1	SCREENING	-21	05NOV2009	12:50	150	90	87	143	99	98	37.1	61
			V1 (WEEK 0)	1	26NOV2009	10:30	144	82	86	138	96	96	36.5	60
			V2 (WEEK 4)	35	30DEC2009	13:45	143	82	116	135	98	116	36.4	61
			V3 (WEEK 12)	85	18FEB2010	10:40	130	77	73	142	94	77	36.9	61
			V4 (WEEK 24)	162	06MAY2010	12:55	156	90	97	140	100	99	36.7	58
			V5 (WEEK 36)	253	05AUG2010	12:20	148	95	85	146	98	93	36.9	58
			V6 (WEEK 52)	366	26NOV2010	10:05	157	87	78	152	89	82	36.7	59
			V7 (WEEK 56)	397	27DEC2010	12:25	161	73	103	155	84	105	37.1	60
	013	4	SCREENING	-30	17AUG2009	13:00	140	80	54	145	85	63	37.3	
			V1 (WEEK 0)	1	16SEP2009	12:30	120	70	70	130	80	73	37.6	68
			V2 (WEEK 4)	29	14OCT2009	10:15	120	80	66	130	85	68	36.8	69
			V3 (WEEK 12)	85	09DEC2009	12:30	130	80	64	135	85	66	36.5	69
			V4 (WEEK 24)	170	04MAR2010	12:00	130	80	64	135	80	66	37.1	69
			V5 (WEEK 36)	247	20MAY2010	12:20	130	80	68	125	80	66	37.0	69
			V6 (WEEK 52)	366	16SEP2010	12:00	130	80	66	130	80	64	36.5	69
			V7 (WEEK 56)	400	20OCT2010	13:00	155	80	72	145	80	72	37.1	68
	016	4	SCREENING	-28	01FEB2010	12:30	130	80	60	125	75	60	37.0	69
			V1 (WEEK 0)	1	01MAR2010	12:30	120	80	55	115	80	58	36.9	69
			V2 (WEEK 4)	29	29MAR2010	12:00	130	80	66	133	80	68	36.6	72
			V3 (WEEK 12)	80	19MAY2010	11:15	130	80	70	130	80	68	37.1	72

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	016	4	V4 (WEEK 24)	162	09AUG2010	12:30	120	80	56	110	80	58	37.1	71
			V5 (WEEK 36)	253	08NOV2010	12:00	120	80	62	130	80	55	36.8	72
			V6 (WEEK 52)	365	28FEB2011	14:45	120	80	64	115	80	62	37.0	72
			V7 (WEEK 56)	403	07APR2011	12:50	150	100	80	130	90	88	37.2	74
	018	5	SCREENING	-20	03NOV2009	13:00	120	80	54	115	80	56	36.1	64
			V1 (WEEK 0)	1	23NOV2009	12:45	140	75	58	130	75	56	36.2	63
			V2 (WEEK 4)	29	21DEC2009	9:10	140	70	60	140	75	64	36.0	64
			V3 (WEEK 12)	86	16FEB2010	9:15	130	70	60	120	70	60	36.7	65
			V4 (WEEK 24)	170	11MAY2010	9:10	140	80	60	130	80	60	36.3	65
			V5 (WEEK 36)	247	27JUL2010	9:00	140	70	52	135	70	56	36.5	63
			V6 (WEEK 52)	366	23NOV2010	9:20	140	70	60	130	70	56	36.0	59
			V7 (WEEK 56)	387	14DEC2010	8:50	130	70	72	120	65	76	36.4	60
	020	5	SCREENING	-26	27JAN2010	15:30	110	70	52	110	70	56	37.0	73
			V1 (WEEK 0)	1	22FEB2010	13:30	130	80	56	120	80	56	36.7	71
	024	4	SCREENING	-31	16JUL2010	12:30	135	70	65	145	80	60	36.5	89
			V1 (WEEK 0)	1	16AUG2010	12:30	165	85	60	150	80	60	36.6	89
			V2 (WEEK 4)	31	15SEP2010	11:30	130	80	72	140	85	66	36.5	91
			V3 (WEEK 12)	87	10NOV2010	10:50	140	80	60	145	80	66	36.5	91
			V4 (WEEK 24)	171	02FEB2011	12:38	140	80	62	145	80	66	36.7	92

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	024	4	V5 (WEEK 36)	246	18APR2011	12:30	140	80	61	160	80	66	36.4	91
			V6 (WEEK 52)	358	08AUG2011	13:30	166	83	59	160	80	60	36.1	92
			V7 (WEEK 56)	393	12SEP2011	13:00	150	80	54	160	80	60	36.7	92
	028	20	SCREENING	-8	18NOV2010	10:00	150	80	76	145	80	74	36.2	65
			V1 (WEEK 0)	1	26NOV2010	11:10	165	85	73	155	85	81	35.1	64
			V2 (WEEK 4)	26	21DEC2010	11:15	140	80	68	140	90	68	34.9	65
			V3 (WEEK 12)	89	22FEB2011	10:15	130	75	84	120	65	96	36.5	66
			V4 (WEEK 24)	180	24MAY2011	10:20	140	90	70	140	90	75	35.9	66
			V5 (WEEK 36)	273	25AUG2011	14:30	140	90	85	140	80	86	36.4	66
			V6 (WEEK 52)	364	24NOV2011	10:45	160	80	74	150	80	76	36.0	65
			V7 (WEEK 56)	390	20DEC2011	10:00	140	80	64	120	80	68	35.9	69
	029	8	SCREENING	-3	26JAN2010	11:40	115	80	72	110	80	78	36.4	
			V1 (WEEK 0)	1	29JAN2010	12:15	110	75	72	110	80	76	36.4	70
			V2 (WEEK 4)	34	03MAR2010	10:25	130	85	68	140	90	76	36.6	64
			V3 (WEEK 12)	82	20APR2010	11:45	140	70	65	145	70	62	36.2	70
			V4 (WEEK 24)	158	05JUL2010	11:20	110	75	64	120	80	66	36.2	70
			V5 (WEEK 36)	245	30SEP2010	12:18	125	75	62	125	65	64	36.7	68
			V6 (WEEK 52)	369	01FEB2011	11:53	100	60	68	105	65	66	36.2	70
			V7 (WEEK 56)	391	23FEB2011	11:15	95	60	62	120	65	60	36.7	70

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	031	8	SCREENING	-14	06MAY2010	13:40	120	65	56	140	70	60	36.3	67
			V1 (WEEK 0)	1	20MAY2010	11:30	110	55	62	115	60	70	36.9	67
			V2 (WEEK 4)	27	15JUN2010	10:45	110	70	68	105	60	70	36.4	67
			V3 (WEEK 12)	90	17AUG2010	10:05	125	60	68	120	65	70	36.2	67
			V4 (WEEK 24)	174	09NOV2010	11:20	130	65	80	110	65	82	36.2	67
			V5 (WEEK 36)	251	25JAN2011	11:45	120	60	70	130	65	68	36.7	68
			V6 (WEEK 52)	363	17MAY2011	11:05	110	70	60	115	70	62	35.9	67
			V7 (WEEK 56)	391	14JUN2011	9:55	105	55	60	110	60	62	36.1	66
	034	9	SCREENING	-22	24FEB2010	8:30	126	74	80	103	81	97	36.0	61
			V1 (WEEK 0)	1	18MAR2010	8:50	137	78	72	125	81	80	35.9	61
			V2 (WEEK 4)	27	13APR2010	10:00	137	87	78	133	86	88	35.4	60
			V3 (WEEK 12)	83	08JUN2010	9:00	126	79	72	130	77	78	34.4	60
			V4 (WEEK 24)	175	08SEP2010	8:45	127	78	79	122	76	91	35.2	60
			V5 (WEEK 36)	258	30NOV2010	8:15	130	76	75	126	78	80	35.3	60
			V6 (WEEK 52)	363	15MAR2011	8:35	134	78	83	119	78	97	35.4	58
			V7 (WEEK 56)	399	20APR2011	8:30	153	86	76	131	86	91	35.4	59
	041	12	SCREENING	-16	23SEP2009	9:00	160	80	72	155	85	84	37.1	
			V1 (WEEK 0)	1	09OCT2009	9:15	170	90	100	170	90	100	37.5	90
			V2 (WEEK 4)	32	09NOV2009	10:30	150	80	80	180	90	84	36.7	
			V3 (WEEK 12)	89	05JAN2010	9:50	160	100	80	190	100	80	37.3	88

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	041	12	V4 (WEEK 24)	167	24MAR2010	9:15	140	80	64	150	80	64	37.0	87
			V5 (WEEK 36)	251	16JUN2010	9:30	150	90	60	160	100	64	36.8	89
			V6 (WEEK 52)	363	06OCT2010	8:35	150	80	68	160	80	72	36.8	84
			V7 (WEEK 56)	392	04NOV2010	8:15	175	85	92	170	85	84	36.9	85
	044	12	SCREENING	-28	04NOV2009	9:30	130	80	80	146	80	84	37.1	
			V1 (WEEK 0)	1	02DEC2009	9:30	120	80	64	130	80	64	36.5	79
			V2 (WEEK 4)	37	07JAN2010	9:40	160	90	80	150	90	84	37.0	80
			V3 (WEEK 12)	85	24FEB2010	9:40	140	90	80	170	90	84	36.7	80
			V4 (WEEK 24)	176	26MAY2010	8:15	130	80	72	130	90	80	36.8	78
			V5 (WEEK 36)	260	18AUG2010	8:15	160	90	80	170	100	84	37.1	80
			V6 (WEEK 52)	365	01DEC2010	9:00	160	100	84	170	100	100	36.9	83
			V7 (WEEK 56)	400	05JAN2011	9:45	120	80	64	130	80	84	37.0	83
	045	11	SCREENING	-14	07DEC2009	9:40	175	95	84	180	80	88	35.8	82
			V1 (WEEK 0)	1	21DEC2009	9:30	135	75	72	145	85	76	36.2	82
			V2 (WEEK 4)	29	18JAN2010	9:30	170	110	72	180	110	72	34.7	83
			V3 (WEEK 12)	85	15MAR2010	8:15	150	80	68	150	90	76	34.9	84
			V4 (WEEK 24)	169	07JUN2010	10:20	125	80	76	130	85	76	36.8	85
			V5 (WEEK 36)	260	06SEP2010	9:15	150	90	72	195	95	80	35.9	86
			V6 (WEEK 52)	360	15DEC2010	10:05	160	100	68	150	95	68	35.7	87
			V7 (WEEK 56)	393	17JAN2011	9:15	120	60	68	130	70	72	35.3	90

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	047	11	SCREENING	-21	12JUL2010	8:00	125	85	76	125	85	76	36.5	76
			V1 (WEEK 0)	1	02AUG2010	9:25	120	70	64	120	75	72	36.5	76
			V2 (WEEK 4)	29	30AUG2010	9:00	120	80	64	120	80	68	36.1	75
			V3 (WEEK 12)	80	20OCT2010	11:35	140	80	64	145	85	72	35.6	75
			V4 (WEEK 24)	162	10JAN2011	9:35	140	80	68	140	85	72	35.9	78
			V5 (WEEK 36)	254	12APR2011	9:20	120	80	76	120	80	80	36.7	77
			V6 (WEEK 52)	360	27JUL2011	7:50	120	80	72	115	80	72	35.9	75
			V7 (WEEK 56)	393	29AUG2011	7:45	110	80	68	110	75	72	36.0	75
	049	21	SCREENING	-51	06SEP2010	11:21	139	49	54	136	61	66	35.5	65
			V1 (WEEK 0)	1	27OCT2010	8:57	162	86	68	156	97	79	35.3	69
			V2 (WEEK 4)	27	22NOV2010	8:35	162	86	63	153	87	72	36.4	70
			V3 (WEEK 12)	84	18JAN2011	10:33	161	103	89	162	101	93	35.6	71
			V4 (WEEK 24)	168	12APR2011	8:25	161	95	74	164	106	78	36.0	73
			V5 (WEEK 36)	252	05JUL2011	9:10	134	89	70	133	86	80	36.9	69
			UNSCHEDULED	286	08AUG2011	11:00	122	87	72					
	051	21	SCREENING	-52	06SEP2010	12:54	137	71	67	147	73	72	35.2	86
			V1 (WEEK 0)	1	28OCT2010	11:40	135	83	70	123	86	73	34.9	85
			V2 (WEEK 4)	27	23NOV2010	9:05	114	81	74	117	83	76	37.1	85
			V3 (WEEK 12)	97	01FEB2011	9:46	126	76	62	126	72	66	36.8	87
			V4 (WEEK 24)	167	12APR2011	13:30	130	93	82	132	92	80	36.7	87

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Listing 16.2.9.1.1: Vital signs / body temperature

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	051	21	V5 (WEEK 36)	251	05JUL2011	13:40	148	98	60	123	102	75	37.1	87
			V6 (WEEK 52)	363	25OCT2011	9:00	138	91	73	134	98	78	36.7	85
			V7 (WEEK 56)	391	22NOV2011	8:25	116	78	73	122	74	79	36.9	83
	056	5	SCREENING	-21	31MAR2010	10:00	170	90	56	165	90	56	36.7	58
			V1 (WEEK 0)	1	21APR2010	9:20	130	80	60	125	80	60	36.3	58
			V2 (WEEK 4)	29	19MAY2010	9:00	130	80	60	120	80	64	36.7	60
			V3 (WEEK 12)	84	13JUL2010	10:30	130	80	56	120	70	60	36.4	55
			V4 (WEEK 24)	168	05OCT2010	9:15	140	90	52	130	80	56	36.1	56
			V5 (WEEK 36)	259	04JAN2011	9:00	130	80	60	120	80	60	36.1	58
			V6 (WEEK 52)	364	19APR2011	8:00	155	86	57	150	80	56	36.2	58
			V7 (WEEK 56)	393	18MAY2011	11:15	160	80	47	170	90	55	36.2	60
	058	1	SCREENING	-21	06DEC2010	9:50	163	99	67	162	95	69	36.4	68
			V1 (WEEK 0)	1	27DEC2010	11:12	159	94	70	162	99	81	36.7	69
			V2 (WEEK 4)	26	21JAN2011	10:45	169	88	65	182	97	75	36.1	72
			V3 (WEEK 12)	93	29MAR2011	10:35	162	90	62	140	98	67	36.2	71
			V4 (WEEK 24)	166	10JUN2011	10:30	141	80	57	138	78	63	36.4	70
			V5 (WEEK 36)	260	12SEP2011	10:10	170	89	68	153	90	67	36.2	69
			V6 (WEEK 52)	345	06DEC2011	10:40	160	84	70	160	84	71	36.6	69
			V7 (WEEK 56)	380	10JAN2012	10:20	148	80	64	161	93	68	36.4	70

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Listing 16.2.9.1.1: Vital signs / body temperature

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	059	1	SCREENING	-2	27DEC2010	13:20	178	100	70	174	99	70	36.3	85
			V1 (WEEK 0)	1	29DEC2010	10:30	172	89	71	173	92	70	36.2	85
			V2 (WEEK 4)	24	21JAN2011	12:00	156	90	71	160	96	71	36.2	85
			V3 (WEEK 12)	93	31MAR2011	9:35	153	82	64	157	80	71	36.4	84
			V4 (WEEK 24)	161	07JUN2011	9:00	162	96	81	158	92	81	36.2	84
			V5 (WEEK 36)	254	08SEP2011	10:00	143	82	76	149	86	80	36.1	84
			V6 (WEEK 52)	345	08DEC2011	10:40	150	88	71	150	88	75	36.0	84
			V7 (WEEK 56)	380	12JAN2012	10:50	144	71	66	147	85	73	36.5	85
	065	16	SCREENING	-20	10AUG2010	11:00	130	82	46	135	80	48	36.3	99
			V1 (WEEK 0)	1	30AUG2010	9:25	134	75	75	130	80	72	36.3	104
			V2 (WEEK 4)	29	27SEP2010	11:30	120	80	72	120	80	68	36.4	102
			V3 (WEEK 12)	85	22NOV2010	10:55	145	60	50	160	70	48	36.1	102
			V4 (WEEK 24)	141	17JAN2011	10:45	145	60	50	150	65	48	36.3	101
	068	16	SCREENING	-27	26OCT2010	8:50	137	86	55	135	85	62	36.3	83
			V1 (WEEK 0)	1	22NOV2010	9:50	125	70	56	120	60	60	35.4	83
			V2 (WEEK 4)	29	20DEC2010	9:45	130	80	72	135	85	68	36.6	83
			V3 (WEEK 12)	81	10FEB2011	9:20	132	88	62	140	90	68	36.0	85
			V4 (WEEK 24)	163	03MAY2011	10:20	145	90	56	150	90	58	36.1	85
			V5 (WEEK 36)	262	10AUG2011	9:05	124	80	60	140	80	64	35.8	84
			V6 (WEEK 52)	372	28NOV2011	10:15	160	90	72	155	85	68	36.3	80

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Listing 16.2.9.1.1: Vital signs / body temperature

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	068	16	V7 (WEEK 56)	414	09JAN2012	11:40	124	91	88	132	74	94	36.8	76
	069	23	SCREENING	-13	24NOV2010	12:00	190	95	90	170	85	80	36.5	90
			V1 (WEEK 0)	1	07DEC2010	12:10	180	90	80	180	90	72	36.5	95
			V2 (WEEK 4)	37	12JAN2011	11:30	190	95	68	160	85	60	36.5	90
			V3 (WEEK 12)	93	09MAR2011	12:15	180	100	62	180	95	62	36.3	98
			V4 (WEEK 24)	164	19MAY2011	12:00	165	90	78	180	95	80	36.2	78
			V5 (WEEK 36)	261	24AUG2011	11:30	180	95	58	180	90	62	36.1	98
			V6 (WEEK 52)	373	14DEC2011	8:45	175	85	80	150	85	74	34.6	97
			V7 (WEEK 56)	401	11JAN2012	8:45	180	90	86	185	90	90	36.3	101
	072	18	SCREENING	-20	01DEC2010	12:15	144	73	56	155	84	63	36.2	71
			V1 (WEEK 0)	1	21DEC2010	11:50	143	67	52	148	72	60	36.0	71
			V2 (WEEK 4)	31	20JAN2011	8:55	128	79	66	148	72	66	36.0	72
			V3 (WEEK 12)	85	15MAR2011	10:00	138	87	52	156	90	55	36.1	71
			V4 (WEEK 24)	169	07JUN2011	10:26	147	87	53	159	94	68	36.3	70
			V5 (WEEK 36)	262	08SEP2011	10:47	127	85	52	132	80	55	36.8	70
			V6 (WEEK 52)	360	15DEC2011	9:51	158	94	51	158	96	50	36.9	73
			V7 (WEEK 56)	393	17JAN2012	9:17	150	87	57	142	90	59	36.3	75
	079	13	SCREENING	-18	19JUL2010	15:05	135	82	50	130	82	51	36.8	73
			V1 (WEEK 0)	1	06AUG2010	10:25	129	75	53	118	74	61	36.6	76

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	079	13	V2 (WEEK 4)	34	08SEP2010	11:16	120	85	51	120	88	53	36.2	78
			V3 (WEEK 12)	96	09NOV2010	12:56	143	84	54	136	86	53	36.2	76
			V4 (WEEK 24)	175	27JAN2011	14:45	161	84	56	143	89	57	36.6	77
			V5 (WEEK 36)	249	11APR2011	11:25	112	79	67	109	77	70	36.6	76
			V6 (WEEK 52)	320	21JUN2011	11:50	134	98	55	117	90	68	36.4	78
			V7 (WEEK 56)	348	19JUL2011	14:30	128	82	48	128	79	56	36.1	75
	082	17	SCREENING	-8	06OCT2010	10:30	128	80	69	133	90	72	36.7	80
			V1 (WEEK 0)	1	14OCT2010	10:20	125	75	72	130	80	79	36.8	80
			V2 (WEEK 4)	35	17NOV2010	10:50	123	70	65	133	83	72	36.8	80
			V3 (WEEK 12)	84	05JAN2011	12:15	120	80	65	130	91	69	36.7	80
			V4 (WEEK 24)	175	06APR2011	9:00	128	90	77	130	93	78	36.7	80
			V5 (WEEK 36)	252	22JUN2011	11:00	125	80	67	133	93	78	36.7	80
			V6 (WEEK 52)	364	12OCT2011	12:00	123	80	73	130	90	80	36.7	80
			V7 (WEEK 56)	407	24NOV2011	9:00	123	80	73	130	90	80	36.6	79
	084	17	SCREENING	-9	08NOV2010	10:25	123	80	72	130	90	80	36.8	70
			V1 (WEEK 0)	1	17NOV2010	12:10	121	72	69	130	82	72	36.8	70
			V2 (WEEK 4)	29	15DEC2010	10:12	121	80	65	130	95	73	36.7	70
			V3 (WEEK 12)	84	08FEB2011	10:30	122	69	65	130	82	75	36.7	72
			V4 (WEEK 24)	175	10MAY2011	10:30	123	81	68	132	90	78	36.6	72
			V5 (WEEK 36)	259	02AUG2011	11:00	122	73	69	130	85	75	36.7	70

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Listing 16.2.9.1.1: Vital signs / body temperature

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Time	Sitting			Standing			Body tem- perature [°C]	Weight [kg]
							SBP [mmHg]	DBP [mmHg]	PR [bpm]	SBP [mmHg]	DBP [mmHg]	PR [bpm]		
Placebo	084	17	V6 (WEEK 52)	371	22NOV2011	11:00	120	80	69	133	85	75	36.7	70
			V7 (WEEK 56)	394	15DEC2011	9:15	123	81	68	132	90	75	37.0	70
	086	21	SCREENING	-24	04OCT2010	11:26	163	112	72	167	122	74	35.6	62
			V1 (WEEK 0)	1	28OCT2010	16:28	157	110	68	165	112	73	35.0	65
			V2 (WEEK 4)	27	23NOV2010	8:12	166	101	72	170	114	80	36.3	65
			V3 (WEEK 12)	83	18JAN2011	11:21	146	109	74	94	56	96	35.9	63
			V4 (WEEK 24)	167	12APR2011	11:46	140	103	73	154	105	81	35.9	63
			V5 (WEEK 36)	251	05JUL2011	12:15	133	98	86	108	86	85	37.3	65
			V6 (WEEK 52)	363	25OCT2011	13:20	166	103	71	164	110	78	34.7	66
			V7 (WEEK 56)	391	22NOV2011	10:24	142	102	80	176	120	74	36.6	66
			SCREENING	-9	30NOV2010	9:50	129	92	72	125	85	68	36.4	67
			V1 (WEEK 0)	1	09DEC2010	9:15	110	75	64	120	80	68	36.4	65
	088	16	V2 (WEEK 4)	27	04JAN2011	10:00	120	80	68	125	85	72	36.3	66
			V3 (WEEK 12)	83	01MAR2011	9:40	110	70	72	115	75	68	36.4	67
			V4 (WEEK 24)	162	19MAY2011	9:20	116	82	77	120	85	72	36.1	66
			V5 (WEEK 36)	264	29AUG2011	9:30	110	70	64	130	75	68	36.1	68
			V6 (WEEK 52)	376	19DEC2011	10:30	120	80	72	125	75	68	36.3	70
			V7 (WEEK 56)	404	16JAN2012	9:15	125	80	72	130	80	68	36.5	70

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	002	1	V2 (WEEK 4) - V1 (WEEK 0)	-12	-12	-2	5	4	-3	-0.4
			V3 (WEEK 12) - V1 (WEEK 0)	0	-6	5	1	-3	14	0.0
			V4 (WEEK 24) - V1 (WEEK 0)	-3	-4	-4	13	5	-5	-0.1
			V5 (WEEK 36) - V1 (WEEK 0)	-7	-6	2	3	-1	5	-0.2
			V6 (WEEK 52) - V1 (WEEK 0)	-10	-11	-3	-13	1	0	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	2	-8	9	11	1	23	0.0
	004	1	V2 (WEEK 4) - V1 (WEEK 0)	-12	-3	2	-7	5	-1	-0.3
			V3 (WEEK 12) - V1 (WEEK 0)	-5	1	-3	7	0	-5	-0.5
	006	2	V2 (WEEK 4) - V1 (WEEK 0)	-5	5	0	-20	-10	8	0.3
			V3 (WEEK 12) - V1 (WEEK 0)	15	5	0	15	0	-4	-0.9
			V4 (WEEK 24) - V1 (WEEK 0)	0	-5	8	-5	-10	4	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	0	0	4	-15	-10	4	0.7
			V6 (WEEK 52) - V1 (WEEK 0)	7	2	7	-22	-2	13	0.3
			V7 (WEEK 56) - V1 (WEEK 0)	17	2	12	-15	-8	17	0.1
	010	1	V2 (WEEK 4) - V1 (WEEK 0)	-21	-5	4	-19	-2	1	0.4
			V3 (WEEK 12) - V1 (WEEK 0)	-9	3	5	-26	1	7	-0.2
	012	1	V2 (WEEK 4) - V1 (WEEK 0)	21	-2	0	8	6	-5	-0.2

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	012	1	V3 (WEEK 12) - V1 (WEEK 0)	11	0	-8	23	6	-13	-0.1
			V4 (WEEK 24) - V1 (WEEK 0)	23	-6	-11	41	0	-17	-0.3
			V5 (WEEK 36) - V1 (WEEK 0)	22	10	-5	22	12	-7	0.1
			V6 (WEEK 52) - V1 (WEEK 0)	26	0	-11	46	5	-15	-0.3
			V7 (WEEK 56) - V1 (WEEK 0)	-9	1	-3	26	6	-7	0.5
	014	4	V2 (WEEK 4) - V1 (WEEK 0)	-10	-10	10	-5	-8	8	0.4
			V3 (WEEK 12) - V1 (WEEK 0)	0	0	4	0	-3	3	0.1
			V4 (WEEK 24) - V1 (WEEK 0)	-5	-5	10	-15	-18	8	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	0	0	-2	-20	-18	0	-0.5
			V6 (WEEK 52) - V1 (WEEK 0)	0	0	-1	-15	-13	0	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	0	0	4	-10	-13	4	-0.1
	015	4	V2 (WEEK 4) - V1 (WEEK 0)	-5	-10	11	5	-5	12	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	35	5	9	40	10	18	0.2
			V4 (WEEK 24) - V1 (WEEK 0)	20	0	7	25	0	18	0.2
			V5 (WEEK 36) - V1 (WEEK 0)	20	5	19	15	0	22	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	10	0	17	15	0	10	-0.2
			V7 (WEEK 56) - V1 (WEEK 0)	18	0	9	25	0	10	-0.5
	017	5	V2 (WEEK 4) - V1 (WEEK 0)	0	-10	-13	0	-10	-20	-0.3

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	017	5	V3 (WEEK 12) - V1 (WEEK 0)	15	-10	-3	0	-10	-8	-0.5
			V4 (WEEK 24) - V1 (WEEK 0)	10	0	0	-10	-10	-4	0.1
			V5 (WEEK 36) - V1 (WEEK 0)	30	0	7	10	-5	0	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	-10	-10	15				
			V7 (WEEK 56) - V1 (WEEK 0)	0	-20	3	0	-10	4	-0.6
	019	5	V2 (WEEK 4) - V1 (WEEK 0)	-10	-10	4	0	-5	12	0.7
			V3 (WEEK 12) - V1 (WEEK 0)	-10	-10	0	0	0	0	0.2
			V4 (WEEK 24) - V1 (WEEK 0)	-20	-20	8	-15	-10	8	0.1
			V5 (WEEK 36) - V1 (WEEK 0)	-20	-20	4	-15	-10	12	0.3
			V6 (WEEK 52) - V1 (WEEK 0)	20	10	12	10	10	20	0.5
			V7 (WEEK 56) - V1 (WEEK 0)	20	0	8	40	10	12	0.5
	023	4	V2 (WEEK 4) - V1 (WEEK 0)	5	0	10	-10	0	6	0.1
			V3 (WEEK 12) - V1 (WEEK 0)	15	5	-5	-10	-5	-8	0.2
			V4 (WEEK 24) - V1 (WEEK 0)	20	0	10	-10	0	10	0.1
			V5 (WEEK 36) - V1 (WEEK 0)	40	10	14	30	20	14	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	25	10	16	0	10	16	0.2
			V7 (WEEK 56) - V1 (WEEK 0)	43	9	13	5	3	15	-0.7
	027	20	V2 (WEEK 4) - V1 (WEEK 0)	-10	-10	-21	-10	10	-3	-0.7

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	027	20	V3 (WEEK 12) - V1 (WEEK 0)	-22	-7	-10	-15	-15	-4	0.7
			V4 (WEEK 24) - V1 (WEEK 0)	-20	-10	-11	-10	-10	-7	0.1
			V5 (WEEK 36) - V1 (WEEK 0)	0	0	3	0	5	1	-0.2
			V6 (WEEK 52) - V1 (WEEK 0)	20	0	-7	30	10	-3	-0.2
			V7 (WEEK 56) - V1 (WEEK 0)	-20	-15	-17	-15	-5	-6	-1.2
	030	8	V2 (WEEK 4) - V1 (WEEK 0)	-25	-5	22	-2	0	36	1.0
			V3 (WEEK 12) - V1 (WEEK 0)	-30	-10	10	10	15	10	-0.1
			V4 (WEEK 24) - V1 (WEEK 0)	-10	0	8	5	-5	12	1.1
			V5 (WEEK 36) - V1 (WEEK 0)	0	5	8	30	5	8	1.0
			V6 (WEEK 52) - V1 (WEEK 0)							
			V7 (WEEK 56) - V1 (WEEK 0)	-40	-10	44	-20	-5	42	0.2
	032	8	V2 (WEEK 4) - V1 (WEEK 0)	-15	5	0	-15	-5	2	0.2
			V3 (WEEK 12) - V1 (WEEK 0)	-10	5	-4	0	5	2	-0.5
	033	9	V2 (WEEK 4) - V1 (WEEK 0)	30	19	8	3	18	8	-0.3
			V3 (WEEK 12) - V1 (WEEK 0)	19	25	15	1	16	8	-0.4
			V4 (WEEK 24) - V1 (WEEK 0)	-13	-5	7	-18	-4	4	-0.6
			V5 (WEEK 36) - V1 (WEEK 0)	9	24	6	-1	5	6	-0.4
			V6 (WEEK 52) - V1 (WEEK 0)	4	4	14	13	4	14	-0.6

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	033	9	V7 (WEEK 56) - V1 (WEEK 0)	18	11	13	-7	22	4	-1.0
	042	12	V2 (WEEK 4) - V1 (WEEK 0)	-40	-20	16	-20	-10	0	-0.2
			V3 (WEEK 12) - V1 (WEEK 0)	-30	-20	16	-20	-20	-4	0.0
			V4 (WEEK 24) - V1 (WEEK 0)	-40	-40	4	-40	-30	-4	-0.2
			V5 (WEEK 36) - V1 (WEEK 0)	-30	-20	0	-30	-10	-20	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	-40	-40	-4	-40	-30	-20	-0.5
			V7 (WEEK 56) - V1 (WEEK 0)	-50	-20	-4	-30	-20	-4	-0.2
	043	12	V2 (WEEK 4) - V1 (WEEK 0)	-10	0	-4	10	0	0	0.8
			V3 (WEEK 12) - V1 (WEEK 0)	-10	0	-4	0	0	-4	1.0
			V4 (WEEK 24) - V1 (WEEK 0)	-30	-10	-16	-20	-10	-14	0.9
			V5 (WEEK 36) - V1 (WEEK 0)	-30	-10	12				
	046	11	V2 (WEEK 4) - V1 (WEEK 0)	0	0	8	0	5	12	1.1
			V3 (WEEK 12) - V1 (WEEK 0)	10	10	20	20	5	20	0.8
			V4 (WEEK 24) - V1 (WEEK 0)	45	25	12	45	20	8	1.1
			V5 (WEEK 36) - V1 (WEEK 0)	20	10	20	15	10	16	0.7
			V6 (WEEK 52) - V1 (WEEK 0)	25	15	12	15	10	12	0.2
			V7 (WEEK 56) - V1 (WEEK 0)	-10	5	12	-20	5	12	0.9

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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13FEB2013

Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	048	11	V2 (WEEK 4) - V1 (WEEK 0)	-25	-10	-4	-25	-15	-4	-0.8
			V3 (WEEK 12) - V1 (WEEK 0)	-30	-10	0	-35	-15	-4	-0.2
			V4 (WEEK 24) - V1 (WEEK 0)	-25	-10	0	-30	-10	0	0.3
			V5 (WEEK 36) - V1 (WEEK 0)	-30	0	0	-30	-5	-4	-0.2
			V6 (WEEK 52) - V1 (WEEK 0)	-40	-10	0	-40	-20	-4	-0.3
			V7 (WEEK 56) - V1 (WEEK 0)	-40	-10	12	-25	-10	0	-0.3
	050	21	V2 (WEEK 4) - V1 (WEEK 0)	8	11	-5	-1	-7	9	2.0
			V3 (WEEK 12) - V1 (WEEK 0)	8	13	5	2	4	4	1.9
			V4 (WEEK 24) - V1 (WEEK 0)	-11	10	6	2	9	4	0.2
			V5 (WEEK 36) - V1 (WEEK 0)	-5	14	-2	2	0	0	2.0
			V6 (WEEK 52) - V1 (WEEK 0)	-12	-4	2				
			V7 (WEEK 56) - V1 (WEEK 0)	-2	3	4	21	7	-1	1.5
	052	21	V2 (WEEK 4) - V1 (WEEK 0)	-10	-2	8	-20	-14	1	1.2
			V3 (WEEK 12) - V1 (WEEK 0)	28	12	6	-2	10	-23	1.3
			V4 (WEEK 24) - V1 (WEEK 0)	36	19	4	6	-2	0	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	16	20	1	-11	-3	-8	0.7
			V6 (WEEK 52) - V1 (WEEK 0)	6	6	8	-12	-6	-2	1.4
			V7 (WEEK 56) - V1 (WEEK 0)	6	9	11	-15	-3	3	1.4

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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13FEB2013

Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	055	5	V2 (WEEK 4) - V1 (WEEK 0)	-5	-10	4	-5	-5	4	0.0
			V2 (WEEK 4) - V1 (WEEK 0)	0	-2	9	-6	-7	8	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	13	4	-2	-4	-9	5	-0.2
			V4 (WEEK 24) - V1 (WEEK 0)	-16	4	3	-15	-5	7	-0.2
	066	16	V2 (WEEK 4) - V1 (WEEK 0)	23	3	8	20	5	0	0.1
			V3 (WEEK 12) - V1 (WEEK 0)	25	1	14	15	2	4	0.3
	067	16	V2 (WEEK 4) - V1 (WEEK 0)	0	-10	0	-5	-15	0	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	0	0	2	-2	-5	0	-0.2
			V4 (WEEK 24) - V1 (WEEK 0)	-20	-10	0	-15	-10	-3	-0.1
	071	18	V2 (WEEK 4) - V1 (WEEK 0)	13	1	5	23	5	2	0.6
			V3 (WEEK 12) - V1 (WEEK 0)	10	12	-1	24	-3	0	-0.4
			V4 (WEEK 24) - V1 (WEEK 0)	7	-2	6	-10	-3	4	0.4
			V5 (WEEK 36) - V1 (WEEK 0)	37	16	-5	15	1	-1	0.0
			V6 (WEEK 52) - V1 (WEEK 0)	21	16	11	18	6	3	0.3
			V7 (WEEK 56) - V1 (WEEK 0)	41	14	13	29	10	7	0.2
	080	13	V2 (WEEK 4) - V1 (WEEK 0)	-12	-13	12	-21	-23	9	1.1

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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13FEB2013

Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	080	13	V3 (WEEK 12) - V1 (WEEK 0)	-8	6	9	-8	2	-3	1.2
			V4 (WEEK 24) - V1 (WEEK 0)	-23	-19	3	13	-13	11	0.9
			V5 (WEEK 36) - V1 (WEEK 0)	-28	-20	-20	-19	-21	-13	0.5
	081	17	V2 (WEEK 4) - V1 (WEEK 0)	-1	1	-1	0	5	-3	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	0	-5	-5	0	-5	-5	0.0
			V4 (WEEK 24) - V1 (WEEK 0)	-3	-5	-1	0	-4	3	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	-1	-10	-5	1	3	-3	0.0
			V6 (WEEK 52) - V1 (WEEK 0)	-3	-5	-1	1	-2	0	0.0
			V7 (WEEK 56) - V1 (WEEK 0)	-2	0	-1	0	5	-3	0.0
	083	17	V2 (WEEK 4) - V1 (WEEK 0)	-3	-8	-3	-1	-5	-3	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	2	-8	-2	2	-10	-3	-0.1
			V4 (WEEK 24) - V1 (WEEK 0)	-1	-3	-3	0	0	-6	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	2	-6	-1	3	-8	-3	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	3	-2	7	1	0	2	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	-1	-8	-2	-2	-10	-3	-0.1
	087	16	V2 (WEEK 4) - V1 (WEEK 0)	0	5	-10	5	13	4	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	-10	5	-14	5	0	0	-1.2
			V4 (WEEK 24) - V1 (WEEK 0)	-10	5	-8	0	8	6	-0.4

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
ACI-91	087	16	V5 (WEEK 36) - V1 (WEEK 0)	-17	1	-14	0	3	0	-1.0
			V6 (WEEK 52) - V1 (WEEK 0)	-20	0	-2	-12	0	12	-0.5
			V7 (WEEK 56) - V1 (WEEK 0)	30	7	-10	32	8	4	-0.5
	089	5	V2 (WEEK 4) - V1 (WEEK 0)	20	10	4	25	0	4	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	0	10	0	-15	-10	-4	0.0
			V4 (WEEK 24) - V1 (WEEK 0)	10	10	0	5	10	-4	-0.2
			V5 (WEEK 36) - V1 (WEEK 0)	3	-3	3	15	-10	1	-0.5
			V6 (WEEK 52) - V1 (WEEK 0)	50	20	-6	50	10	-10	-0.3
			V7 (WEEK 56) - V1 (WEEK 0)	6	10	3	17	20	0	0.0
	093	17	V2 (WEEK 4) - V1 (WEEK 0)	-5	10	0	0	11	3	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	-7	-4	2	-12	-11	2	0.0
			V4 (WEEK 24) - V1 (WEEK 0)	-3	2	4	0	-2	1	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	0	1	-2	1	7	5	0.0
			V6 (WEEK 52) - V1 (WEEK 0)	-5	10	3	2	8	5	0.0
			V7 (WEEK 56) - V1 (WEEK 0)	-5	10	2	0	9	2	0.1
	097	12	V2 (WEEK 4) - V1 (WEEK 0)	-20	0	-20	-20	0	0	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	0	10	0	0	10	0	-0.4

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	001	1	V2 (WEEK 4) - V1 (WEEK 0)	-9	-15	6	22	3	12	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	-7	-15	-1	-16	0	-2	-0.6
			V4 (WEEK 24) - V1 (WEEK 0)	-15	-8	-3	-25	7	1	-0.1
			V5 (WEEK 36) - V1 (WEEK 0)	1	-7	-7	-11	2	-3	-0.5
			V6 (WEEK 52) - V1 (WEEK 0)	-4	-11	-12	-10	-6	-12	0.2
			V7 (WEEK 56) - V1 (WEEK 0)	-20	-17	-13	-22	2	-5	-0.5
	003	1	V2 (WEEK 4) - V1 (WEEK 0)	-63	-21	-13	-40	-17	-1	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	-48	-16	-13	-40	-17	-5	0.1
			V4 (WEEK 24) - V1 (WEEK 0)	-28	-16	-13	-25	-17	-13	-0.2
	005	2	V2 (WEEK 4) - V1 (WEEK 0)	-70	-35	8	-35	-20	16	-0.8
			V3 (WEEK 12) - V1 (WEEK 0)	-40	-20	4	-25	-15	8	
			V4 (WEEK 24) - V1 (WEEK 0)	-50	-25	4	-35	-10	8	-1.1
			V5 (WEEK 36) - V1 (WEEK 0)	-45	-20	8	-20	-5	12	-0.8
			V6 (WEEK 52) - V1 (WEEK 0)	-45	-20	8	-30	-5	20	-1.5
			V7 (WEEK 56) - V1 (WEEK 0)	-65	-30	12	-45	-15	16	-1.0
	009	1	V2 (WEEK 4) - V1 (WEEK 0)	7	5	-3	-6	6	-6	-0.8
			V3 (WEEK 12) - V1 (WEEK 0)	35	7	-3	18	9	0	-0.7
			V4 (WEEK 24) - V1 (WEEK 0)	14	4	-12	10	6	-9	-0.2

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	009	1	V5 (WEEK 36) - V1 (WEEK 0)	33	11	-5	19	13	-11	-0.8
			V6 (WEEK 52) - V1 (WEEK 0)	5	3	-9	6	4	-5	0.0
			V7 (WEEK 56) - V1 (WEEK 0)	9	5	1	6	7	-2	-0.3
	011	1	V2 (WEEK 4) - V1 (WEEK 0)	-1	0	30	-3	2	20	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	-14	-5	-13	4	-2	-19	0.4
			V4 (WEEK 24) - V1 (WEEK 0)	12	8	11	2	4	3	0.2
			V5 (WEEK 36) - V1 (WEEK 0)	4	13	-1	8	2	-3	0.4
			V6 (WEEK 52) - V1 (WEEK 0)	13	5	-8	14	-7	-14	0.2
			V7 (WEEK 56) - V1 (WEEK 0)	17	-9	17	17	-12	9	0.6
	013	4	V2 (WEEK 4) - V1 (WEEK 0)	0	10	-4	0	5	-5	-0.8
			V3 (WEEK 12) - V1 (WEEK 0)	10	10	-6	5	5	-7	-1.1
			V4 (WEEK 24) - V1 (WEEK 0)	10	10	-6	5	0	-7	-0.5
			V5 (WEEK 36) - V1 (WEEK 0)	10	10	-2	-5	0	-7	-0.6
			V6 (WEEK 52) - V1 (WEEK 0)	10	10	-4	0	0	-9	-1.1
			V7 (WEEK 56) - V1 (WEEK 0)	35	10	2	15	0	-1	-0.5
	016	4	V2 (WEEK 4) - V1 (WEEK 0)	10	0	11	18	0	10	-0.3
			V3 (WEEK 12) - V1 (WEEK 0)	10	0	15	15	0	10	0.2
			V4 (WEEK 24) - V1 (WEEK 0)	0	0	1	-5	0	0	0.2

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	016	4	V5 (WEEK 36) - V1 (WEEK 0)	0	0	7	15	0	-3	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	0	0	9	0	0	4	0.1
			V7 (WEEK 56) - V1 (WEEK 0)	30	20	25	15	10	30	0.3
	018	5	V2 (WEEK 4) - V1 (WEEK 0)	0	-5	2	10	0	8	-0.2
			V3 (WEEK 12) - V1 (WEEK 0)	-10	-5	2	-10	-5	4	0.5
			V4 (WEEK 24) - V1 (WEEK 0)	0	5	2	0	5	4	0.1
			V5 (WEEK 36) - V1 (WEEK 0)	0	-5	-6	5	-5	0	0.3
			V6 (WEEK 52) - V1 (WEEK 0)	0	-5	2	0	-5	0	-0.2
			V7 (WEEK 56) - V1 (WEEK 0)	-10	-5	14	-10	-10	20	0.2
	024	4	V2 (WEEK 4) - V1 (WEEK 0)	-35	-5	12	-10	5	6	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	-25	-5	0	-5	0	6	-0.1
			V4 (WEEK 24) - V1 (WEEK 0)	-25	-5	2	-5	0	6	0.1
			V5 (WEEK 36) - V1 (WEEK 0)	-25	-5	1	10	0	6	-0.2
			V6 (WEEK 52) - V1 (WEEK 0)	1	-2	-1	10	0	0	-0.5
			V7 (WEEK 56) - V1 (WEEK 0)	-15	-5	-6	10	0	0	0.1
	028	20	V2 (WEEK 4) - V1 (WEEK 0)	-25	-5	-5	-15	5	-13	-0.2
			V3 (WEEK 12) - V1 (WEEK 0)	-35	-10	11	-35	-20	15	1.4
			V4 (WEEK 24) - V1 (WEEK 0)	-25	5	-3	-15	5	-6	0.8

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	028	20	V5 (WEEK 36) - V1 (WEEK 0)	-25	5	12	-15	-5	5	1.3
			V6 (WEEK 52) - V1 (WEEK 0)	-5	-5	1	-5	-5	-5	0.9
			V7 (WEEK 56) - V1 (WEEK 0)	-25	-5	-9	-35	-5	-13	0.8
	029	8	V2 (WEEK 4) - V1 (WEEK 0)	20	10	-4	30	10	0	0.2
			V3 (WEEK 12) - V1 (WEEK 0)	30	-5	-7	35	-10	-14	-0.2
			V4 (WEEK 24) - V1 (WEEK 0)	0	0	-8	10	0	-10	-0.2
			V5 (WEEK 36) - V1 (WEEK 0)	15	0	-10	15	-15	-12	0.3
			V6 (WEEK 52) - V1 (WEEK 0)	-10	-15	-4	-5	-15	-10	-0.2
			V7 (WEEK 56) - V1 (WEEK 0)	-15	-15	-10	10	-15	-16	0.3
	031	8	V2 (WEEK 4) - V1 (WEEK 0)	0	15	6	-10	0	0	-0.5
			V3 (WEEK 12) - V1 (WEEK 0)	15	5	6	5	5	0	-0.7
			V4 (WEEK 24) - V1 (WEEK 0)	20	10	18	-5	5	12	-0.7
			V5 (WEEK 36) - V1 (WEEK 0)	10	5	8	15	5	-2	-0.2
			V6 (WEEK 52) - V1 (WEEK 0)	0	15	-2	0	10	-8	-1.0
			V7 (WEEK 56) - V1 (WEEK 0)	-5	0	-2	-5	0	-8	-0.8
	034	9	V2 (WEEK 4) - V1 (WEEK 0)	11	4	-8	22	0	-17	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	0	5	-8	27	-4	-19	-1.6
			V4 (WEEK 24) - V1 (WEEK 0)	1	4	-1	19	-5	-6	-0.8

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	034	9	V5 (WEEK 36) - V1 (WEEK 0)	4	2	-5	23	-3	-17	-0.7
			V6 (WEEK 52) - V1 (WEEK 0)	8	4	3	16	-3	0	-0.6
			V7 (WEEK 56) - V1 (WEEK 0)	27	12	-4	28	5	-6	-0.6
	041	12	V2 (WEEK 4) - V1 (WEEK 0)	-20	-10	-20	10	0	-16	-0.8
			V3 (WEEK 12) - V1 (WEEK 0)	-10	10	-20	20	10	-20	-0.2
			V4 (WEEK 24) - V1 (WEEK 0)	-30	-10	-36	-20	-10	-36	-0.5
			V5 (WEEK 36) - V1 (WEEK 0)	-20	0	-40	-10	10	-36	-0.7
			V6 (WEEK 52) - V1 (WEEK 0)	-20	-10	-32	-10	-10	-28	-0.7
			V7 (WEEK 56) - V1 (WEEK 0)	5	-5	-8	0	-5	-16	-0.6
	044	12	V2 (WEEK 4) - V1 (WEEK 0)	40	10	16	20	10	20	0.5
			V3 (WEEK 12) - V1 (WEEK 0)	20	10	16	40	10	20	0.2
			V4 (WEEK 24) - V1 (WEEK 0)	10	0	8	0	10	16	0.3
			V5 (WEEK 36) - V1 (WEEK 0)	40	10	16	40	20	20	0.6
			V6 (WEEK 52) - V1 (WEEK 0)	40	20	20	40	20	36	0.4
			V7 (WEEK 56) - V1 (WEEK 0)	0	0	0	0	0	20	0.5
	045	11	V2 (WEEK 4) - V1 (WEEK 0)	35	35	0	35	25	-4	-1.5
			V3 (WEEK 12) - V1 (WEEK 0)	15	5	-4	5	5	0	-1.3
			V4 (WEEK 24) - V1 (WEEK 0)	-10	5	4	-15	0	0	0.6

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	045	11	V5 (WEEK 36) - V1 (WEEK 0)	15	15	0	50	10	4	-0.3
			V6 (WEEK 52) - V1 (WEEK 0)	25	25	-4	5	10	-8	-0.5
			V7 (WEEK 56) - V1 (WEEK 0)	-15	-15	-4	-15	-15	-4	-0.9
	047	11	V2 (WEEK 4) - V1 (WEEK 0)	0	10	0	0	5	-4	-0.4
			V3 (WEEK 12) - V1 (WEEK 0)	20	10	0	25	10	0	-0.9
			V4 (WEEK 24) - V1 (WEEK 0)	20	10	4	20	10	0	-0.6
			V5 (WEEK 36) - V1 (WEEK 0)	0	10	12	0	5	8	0.2
			V6 (WEEK 52) - V1 (WEEK 0)	0	10	8	-5	5	0	-0.6
			V7 (WEEK 56) - V1 (WEEK 0)	-10	10	4	-10	0	0	-0.5
	049	21	V2 (WEEK 4) - V1 (WEEK 0)	0	0	-5	-3	-10	-7	1.1
			V3 (WEEK 12) - V1 (WEEK 0)	-1	17	21	6	4	14	0.3
			V4 (WEEK 24) - V1 (WEEK 0)	-1	9	6	8	9	-1	0.7
			V5 (WEEK 36) - V1 (WEEK 0)	-28	3	2	-23	-11	1	1.6
			V6 (WEEK 52) - V1 (WEEK 0)	-40	1	4				
	051	21	V2 (WEEK 4) - V1 (WEEK 0)	-21	-2	4	-6	-3	3	2.2
			V3 (WEEK 12) - V1 (WEEK 0)	-9	-7	-8	3	-14	-7	1.9
			V4 (WEEK 24) - V1 (WEEK 0)	-5	10	12	9	6	7	1.8
			V5 (WEEK 36) - V1 (WEEK 0)	13	15	-10	0	16	2	2.2

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	051	21	V6 (WEEK 52) - V1 (WEEK 0)	3	8	3	11	12	5	1.8
			V7 (WEEK 56) - V1 (WEEK 0)	-19	-5	3	-1	-12	6	2.0
	056	5	V2 (WEEK 4) - V1 (WEEK 0)	0	0	0	-5	0	4	0.4
			V3 (WEEK 12) - V1 (WEEK 0)	0	0	-4	-5	-10	0	0.1
			V4 (WEEK 24) - V1 (WEEK 0)	10	10	-8	5	0	-4	-0.2
			V5 (WEEK 36) - V1 (WEEK 0)	0	0	0	-5	0	0	-0.2
			V6 (WEEK 52) - V1 (WEEK 0)	25	6	-3	25	0	-4	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	30	0	-13	45	10	-5	-0.1
	058	1	V2 (WEEK 4) - V1 (WEEK 0)	10	-6	-5	20	-2	-6	-0.6
			V3 (WEEK 12) - V1 (WEEK 0)	3	-4	-8	-22	-1	-14	-0.5
			V4 (WEEK 24) - V1 (WEEK 0)	-18	-14	-13	-24	-21	-18	-0.3
			V5 (WEEK 36) - V1 (WEEK 0)	11	-5	-2	-9	-9	-14	-0.5
			V6 (WEEK 52) - V1 (WEEK 0)	1	-10	0	-2	-15	-10	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	-11	-14	-6	-1	-6	-13	-0.3
	059	1	V2 (WEEK 4) - V1 (WEEK 0)	-16	1	0	-13	4	1	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	-19	-7	-7	-16	-12	1	0.2
			V4 (WEEK 24) - V1 (WEEK 0)	-10	7	10	-15	0	11	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	-29	-7	5	-24	-6	10	-0.1

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	059	1	V6 (WEEK 52) - V1 (WEEK 0)	-22	-1	0	-23	-4	5	-0.2
			V7 (WEEK 56) - V1 (WEEK 0)	-28	-18	-5	-26	-7	3	0.3
	065	16	V2 (WEEK 4) - V1 (WEEK 0)	-14	5	-3	-10	0	-4	0.1
			V3 (WEEK 12) - V1 (WEEK 0)	11	-15	-25	30	-10	-24	-0.2
			V4 (WEEK 24) - V1 (WEEK 0)	11	-15	-25	20	-15	-24	0.0
	068	16	V2 (WEEK 4) - V1 (WEEK 0)	5	10	16	15	25	8	1.2
			V3 (WEEK 12) - V1 (WEEK 0)	7	18	6	20	30	8	0.6
			V4 (WEEK 24) - V1 (WEEK 0)	20	20	0	30	30	-2	0.7
			V5 (WEEK 36) - V1 (WEEK 0)	-1	10	4	20	20	4	0.4
			V6 (WEEK 52) - V1 (WEEK 0)	35	20	16	35	25	8	0.9
			V7 (WEEK 56) - V1 (WEEK 0)	-1	21	32	12	14	34	1.4
	069	23	V2 (WEEK 4) - V1 (WEEK 0)	10	5	-12	-20	-5	-12	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	0	10	-18	0	5	-10	-0.2
			V4 (WEEK 24) - V1 (WEEK 0)	-15	0	-2	0	5	8	-0.3
			V5 (WEEK 36) - V1 (WEEK 0)	0	5	-22	0	0	-10	-0.4
			V6 (WEEK 52) - V1 (WEEK 0)	-5	-5	0	-30	-5	2	-1.9
			V7 (WEEK 56) - V1 (WEEK 0)	0	0	6	5	0	18	-0.2

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SBP=systolic blood pressure, DBP=diastolic blood pressure

Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	072	18	V2 (WEEK 4) - V1 (WEEK 0)	-15	12	14	0	0	6	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	-5	20	0	8	18	-5	0.1
			V4 (WEEK 24) - V1 (WEEK 0)	4	20	1	11	22	8	0.3
			V5 (WEEK 36) - V1 (WEEK 0)	-16	18	0	-16	8	-5	0.8
			V6 (WEEK 52) - V1 (WEEK 0)	15	27	-1	10	24	-10	0.9
			V7 (WEEK 56) - V1 (WEEK 0)	7	20	5	-6	18	-1	0.3
	079	13	V2 (WEEK 4) - V1 (WEEK 0)	-9	10	-2	2	14	-8	-0.4
			V3 (WEEK 12) - V1 (WEEK 0)	14	9	1	18	12	-8	-0.4
			V4 (WEEK 24) - V1 (WEEK 0)	32	9	3	25	15	-4	0.0
			V5 (WEEK 36) - V1 (WEEK 0)	-17	4	14	-9	3	9	0.0
			V6 (WEEK 52) - V1 (WEEK 0)	5	23	2	-1	16	7	-0.2
			V7 (WEEK 56) - V1 (WEEK 0)	-1	7	-5	10	5	-5	-0.5
	082	17	V2 (WEEK 4) - V1 (WEEK 0)	-2	-5	-7	3	3	-7	0.0
			V3 (WEEK 12) - V1 (WEEK 0)	-5	5	-7	0	11	-10	-0.1
			V4 (WEEK 24) - V1 (WEEK 0)	3	15	5	0	13	-1	-0.1
			V5 (WEEK 36) - V1 (WEEK 0)	0	5	-5	3	13	-1	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	-2	5	1	0	10	1	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	-2	5	1	0	10	1	-0.2

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Listing 16.2.9.1.2: Vital signs / body temperature. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	Sitting			Standing			Body Tempe- rature [°C]
				SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	SBP (mmHg)	DBP (mmHg)	Pulse rate (bpm)	
Placebo	084	17	V2 (WEEK 4) - V1 (WEEK 0)	0	8	-4	0	13	1	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	1	-3	-4	0	0	3	-0.1
			V4 (WEEK 24) - V1 (WEEK 0)	2	9	-1	2	8	6	-0.2
			V5 (WEEK 36) - V1 (WEEK 0)	1	1	0	0	3	3	-0.1
			V6 (WEEK 52) - V1 (WEEK 0)	-1	8	0	3	3	3	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	2	9	-1	2	8	3	0.2
	086	21	V2 (WEEK 4) - V1 (WEEK 0)	9	-9	4	5	2	7	1.3
			V3 (WEEK 12) - V1 (WEEK 0)	-11	-1	6	-71	-56	23	0.9
			V4 (WEEK 24) - V1 (WEEK 0)	-17	-7	5	-11	-7	8	0.9
			V5 (WEEK 36) - V1 (WEEK 0)	-24	-12	18	-57	-26	12	2.3
			V6 (WEEK 52) - V1 (WEEK 0)	9	-7	3	-1	-2	5	-0.3
			V7 (WEEK 56) - V1 (WEEK 0)	-15	-8	12	11	8	1	1.6
	088	16	V2 (WEEK 4) - V1 (WEEK 0)	10	5	4	5	5	4	-0.1
			V3 (WEEK 12) - V1 (WEEK 0)	0	-5	8	-5	-5	0	0.0
			V4 (WEEK 24) - V1 (WEEK 0)	6	7	13	0	5	4	-0.3
			V5 (WEEK 36) - V1 (WEEK 0)	0	-5	0	10	-5	0	-0.3
			V6 (WEEK 52) - V1 (WEEK 0)	10	5	8	5	-5	0	-0.1
			V7 (WEEK 56) - V1 (WEEK 0)	15	5	8	10	0	0	0.1

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SBP=systolic blood pressure, DBP=diastolic blood pressure

Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	002	1	SCREENING	02APR2009	71	106	86	382	417	405	838	NORMAL VARIANT
			V1 (WEEK 0)	23APR2009	57	102	87	411	408	409	1020	NORMAL VARIANT
			V3 (WEEK 12)	16JUL2009	61	114	87	399	405	403	970	NORMAL VARIANT
			V4 (WEEK 24)	08OCT2009	62	115	84	398	406	403	962	NORMAL VARIANT
			V5 (WEEK 36)	05JAN2010	65	105	84	397	412	407	926	NORMAL VARIANT
			V6 (WEEK 52)	22APR2010	61	80	87	406	409	409	983	ABNORMAL
	004	1	SCREENING	17JUN2009	59	141	94	410	451	447	980	NORMAL VARIANT
			V1 (WEEK 0)	16JUL2009	58	153	94	424	418	420	1030	NORMAL VARIANT
			V3 (WEEK 12)	15OCT2009	64	140	99	406	419	415	937	NORMAL
	006	2	SCREENING	25JAN2010	64	148	89	378	385	381	929	
			V1 (WEEK 0)	26FEB2010	68	164	88	363	386	379	895	
			V3 (WEEK 12)	21MAY2010	67	168	89	380	397	393	943	ABNORMAL
			V4 (WEEK 24)	13AUG2010	67	169	89	392	408	404	954	NORMAL
			V5 (WEEK 36)	04NOV2010	67	162	87	362	379	373	911	NORMAL
			V6 (WEEK 52)	24FEB2011	64	166	85	378	384	381	951	NORMAL VARIANT

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	002	1	SCREENING	EVALUABLE		25 mm/sec. recording speed
			V1 (WEEK 0)	EVALUABLE		25 mm/sec. recording speed
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	004	1	SCREENING	NOT EVALUABLE	OTHER	25 mm/sec. recording speed
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
	006	2	SCREENING	NOT EVALUABLE	REVERSAL LIMB LEADS	Reversal right arm - left leg cables. ND=not done. No conclusion and interpretation possible.
			V1 (WEEK 0)	NOT EVALUABLE	REVERSAL LIMB LEADS	Reversal left arm - right leg cables. ND=not done. No conclusion and interpretation possible.
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		ND=not done.
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		ND = not done

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	010	1	SCREENING	26JUN2009	53	197	110	508	478	488	1130	ABNORMAL
			V1 (WEEK 0)	21JUL2009	50	196	112	517	483	497	1193	ABNORMAL
			V3 (WEEK 12)	13OCT2009	56	182	110	443	429	433	1067	NORMAL VARIANT
	012	1	SCREENING	17JUN2010	51	158	137	446	413	424	1165	ABNORMAL
			UNSCHEDULED	18AUG2011	53	157	145	443	420	428	1116	ABNORMAL
			V1 (WEEK 0)	19JUL2010	49	156	142	458	416	429	1212	ABNORMAL
			V3 (WEEK 12)	14OCT2010	42	151	138	476	407	429	1367	ABNORMAL
			V4 (WEEK 24)	10JAN2011	42	156	146	473	397	421	1418	ABNORMAL
			V5 (WEEK 36)	01APR2011	52	164	143	461	431	441	1144	ABNORMAL
	014	4	SCREENING	07OCT2009	65	179	73	376	392	384	918	NORMAL VARIANT
			V1 (WEEK 0)	02NOV2009	56	180	72	395	380	385	1079	NORMAL VARIANT
			V3 (WEEK 12)	25JAN2010	59	178	74	396	395	395	1009	NORMAL VARIANT
			V4 (WEEK 24)	22APR2010	60	180	76	391	388	389	1018	NORMAL VARIANT
			V5 (WEEK 36)	15JUL2010	54	180	79	471	426	441	1219	NORMAL VARIANT
			V6 (WEEK 52)	28OCT2010	58	170	74	379	375	376	1025	NORMAL VARIANT
	015	4	SCREENING	21JAN2010	53	186	80	443	416	425	1135	NORMAL VARIANT
			V1 (WEEK 0)	22FEB2010	49	178	80	451	391	410	1330	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	010	1	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
	012	1	SCREENING	EVALUABLE		
			UNSCHEDULED	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
	014	4	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		No data of heart axis. Heart axis absent. The data of the heart axis is missing. Electronic oscillations (mush) on lead II: wrong results of measurement are possible.
	015	4	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	015	4	V3 (WEEK 12)	17MAY2010	55	174	78	427	411	416	1082	NORMAL VARIANT
			V4 (WEEK 24)	02AUG2010	52	181	85	432	408	416	1117	NORMAL VARIANT
			V5 (WEEK 36)	27OCT2010	56	179	84	425	411	415	1067	NORMAL VARIANT
			V6 (WEEK 52)	21FEB2011	52	187	82	416	391	399	1130	NORMAL VARIANT
	017	5	SCREENING	14JUL2009	88	159	93	365	453	422	650	ABNORMAL
			V1 (WEEK 0)	05AUG2009	81	160	101	372	436	413	729	NORMAL VARIANT
			V3 (WEEK 12)	28OCT2009	78	162	100	358	410	392	764	NORMAL VARIANT
			V4 (WEEK 24)	20JAN2010	81	160	101	385	451	428	728	ABNORMAL
			V5 (WEEK 36)	13APR2010	90	159	101	391	480	448	663	ABNORMAL
			V6 (WEEK 52)	03AUG2010	85							
	019	5	SCREENING	18NOV2009	58	213	100	398	402	400	985	NORMAL VARIANT
			V1 (WEEK 0)	09DEC2009	65	222	100	374	392	386	909	NORMAL VARIANT
			V3 (WEEK 12)	03MAR2010	63	246	108	387	402	397	925	NORMAL VARIANT
			V4 (WEEK 24)	25MAY2010	70	232	114	370	402	391	848	ABNORMAL
			V5 (WEEK 36)	24AUG2010	68	193	103	353	377	369	875	NORMAL VARIANT
			V6 (WEEK 52)	07DEC2010	76	204	111	358	408	390	770	ABNORMAL
	023	4	SCREENING	01JUL2010	56	144	95	429	409	417	1051	NORMAL VARIANT
			V1 (WEEK 0)	20JUL2010	54	144	81	436	409	417	1139	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	015	4	V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		Heart axis absent.
			V5 (WEEK 36)	EVALUABLE		The data of the heart axis are missing.
			V6 (WEEK 52)	EVALUABLE		The data of heart axis are missing.
	017	5	SCREENING	EVALUABLE		The recording speed is 25 mm/sec.
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	NOT EVALUABLE	REVERSAL LIMB LEADS	Right arm and right leg cable reversal.
	019	5	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	023	4	SCREENING	EVALUABLE		Heart axis absent.
			V1 (WEEK 0)	EVALUABLE		

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	023	4	V3 (WEEK 12)	13OCT2010	68	129	90	364	388	379	880	NORMAL
			V4 (WEEK 24)	12JAN2011	63	145	80	396	414	408	913	NORMAL VARIANT
			V5 (WEEK 36)	21MAR2011	67	135	84	424	440	432	898	NORMAL VARIANT
	027	20	V6 (WEEK 52)	18JUL2011	74	135	83	400	455	436	774	NORMAL VARIANT
			SCREENING	30SEP2010	67	144	84	384	403	396	910	NORMAL VARIANT
			V1 (WEEK 0)	21OCT2010	67	149	83	394	415	408	900	NORMAL VARIANT
			V3 (WEEK 12)	20JAN2011	73	145	81	377	415	402	825	NORMAL VARIANT
			V4 (WEEK 24)	12APR2011	71	147	84	380	425	409	799	NORMAL VARIANT
			V5 (WEEK 36)	06JUN2011	80	140	85	352	410	390	737	NORMAL VARIANT
	030	8	V6 (WEEK 52)	25OCT2011	73	140	84	384	427	412	811	NORMAL VARIANT
			SCREENING	18MAR2010	50	176	84	427	391	402	1193	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	023	4	V3 (WEEK 12)	EVALUABLE		Missing heart axis data. Electronic oscillations (mush) in lead II: wrong results of measurement are possible. The heart axis are missing. The data of the heart axis are missing. Electronic oscillations (mush) and undulating line in lead II: wrong results of measurement and interpretation are possible. Electronic oscillations (mush) in lead II: wrong results of measurement are possible. The data of the heart axis are missing.
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	027	20	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	030	8	SCREENING	EVALUABLE		

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	030	8	V1 (WEEK 0)	25MAR2010	49	145	84	438	404	415	1175	NORMAL VARIANT
			V3 (WEEK 12)	17JUN2010	53	168	86	398	375	382	1129	NORMAL VARIANT
			V4 (WEEK 24)	03SEP2010	57	163	85	397	391	393	1030	NORMAL VARIANT
			V5 (WEEK 36)	02DEC2010	56	163	85	368	357	361	1064	NORMAL VARIANT
			V6 (WEEK 52)	14MAR2011	54	169	85	402	384	390	1099	NORMAL VARIANT
	032	8	SCREENING	08NOV2010	55	130	90	394	380	384	1081	NORMAL VARIANT
			V1 (WEEK 0)	18NOV2010	56	130	88	387	378	381	1053	NORMAL VARIANT
			V3 (WEEK 12)	07FEB2011	54	130	90	396	382	386	1077	NORMAL VARIANT
	033	9	SCREENING	28OCT2009	65	147	91	380	403	395	890	NORMAL VARIANT
			V1 (WEEK 0)	04NOV2009	57	140	90	408	402	404	1030	NORMAL VARIANT
			V3 (WEEK 12)	20JAN2010	60	148	90	424	412	412	1004	NORMAL VARIANT
			V4 (WEEK 24)	21APR2010	54	163	92	446	425	432	1102	NORMAL VARIANT
			V6 (WEEK 52)	10NOV2010	72	162	88	378	420	406	808	NORMAL
	042	12	SCREENING	16DEC2009		109	82	338	365	356	855	
			V1 (WEEK 0)	14JAN2010	87	100	84	318	388	363	668	NORMAL VARIANT
			V3 (WEEK 12)	14MAY2010	73	100	90	343	388	372	785	NORMAL VARIANT

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	030	8	V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	032	8	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
	033	9	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	042	12	SCREENING	NOT EVALUABLE	LEAD(S) NOT AVAILABLE	ND = not done. Heart axis missing. Precordial leads missing. Limb leads: insufficient quality. Overall conclusion impossible. The precordial leads are not available.
			V1 (WEEK 0)	NOT EVALUABLE	LEAD(S) NOT AVAILABLE	
			V3 (WEEK 12)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	042	12	V4 (WEEK 24)	30JUN2010	66	112	87	351	381	371	851	NORMAL VARIANT
			V5 (WEEK 36)	22SEP2010	97	103	83	331	421	389	616	NORMAL VARIANT
			V6 (WEEK 52)	12JAN2011	74	106	83	352	399	382	780	NORMAL VARIANT
	043	12	SCREENING	21OCT2009	84	170	124	343	407	385	710	ABNORMAL
			V1 (WEEK 0)	18NOV2009	78	172	134	371	438	414	717	ABNORMAL
			V3 (WEEK 12)	10FEB2010	61	140	134	409	415	413	972	ABNORMAL
			V4 (WEEK 24)	12MAY2010	75	157	132	376	417	403	814	ABNORMAL
	046	11	SCREENING	14DEC2009	96	202	82	350	414	391	620	NORMAL VARIANT
			V1 (WEEK 0)	11JAN2010	84	203	78	350	414	391	717	ABNORMAL
			V3 (WEEK 12)	07APR2010	84	232	81	349	414	391	712	ABNORMAL
			V4 (WEEK 24)	07JUL2010	83	220	83	375	443	420	715	ABNORMAL
			V5 (WEEK 36)	22SEP2010	92	211	81	340	421	392	652	ABNORMAL
			V6 (WEEK 52)	12JAN2011	92	214	83	369	462	428	638	ABNORMAL
	048	11	SCREENING	17NOV2010	63	174	118	398	418	412	905	NORMAL VARIANT
			V1 (WEEK 0)	22NOV2010	61	174	119	401	399	399	1007	NORMAL VARIANT
			V3 (WEEK 12)	15FEB2011	69	175	113	385	415	405	860	NORMAL VARIANT
			V4 (WEEK 24)	16MAY2011	57	174	111	414	404	407	1048	NORMAL VARIANT
			V5 (WEEK 36)	26JUL2011	54	183	112	403	386	391	1089	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	042	12	V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	043	12	SCREENING	EVALUABLE		The data of the heart axis are absent.
			V1 (WEEK 0)	EVALUABLE		The data of the heart axis are absent.
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
	046	11	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	048	11	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	048	11	V6 (WEEK 52)	16NOV2011	58	185	113	387	382	383	1025	NORMAL VARIANT
	050	21	SCREENING	06SEP2010	56	142	94	407	405	406	1011	NORMAL VARIANT
			V1 (WEEK 0)	27OCT2010	57	141	94	407	395	399	1063	NORMAL VARIANT
			V3 (WEEK 12)	17JAN2011	59	150	93	409	398	402	1052	NORMAL VARIANT
			V4 (WEEK 24)	11APR2011	58	167	105	433	424	427	1045	NORMAL
			V5 (WEEK 36)	04JUL2011	67	149	97	415	424	421	956	NORMAL VARIANT
			V6 (WEEK 52)	04OCT2011	60	186	97	404	412	409	963	NORMAL VARIANT
	052	21	SCREENING	06SEP2010	65	180	83	397	434	421	836	NORMAL VARIANT
			V1 (WEEK 0)	28OCT2010	65	158	82	409	437	428	874	NORMAL VARIANT
			V3 (WEEK 12)	17JAN2011	57	173	92	426	421	423	1021	

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	048	11	V6 (WEEK 52)	EVALUABLE		
	050	21	SCREENING	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent.
			V1 (WEEK 0)	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent.
			V3 (WEEK 12)	EVALUABLE		Heart axis is missing. Speed 25 mm/s
			V4 (WEEK 24)	EVALUABLE		Rec. speed 25 mm/s. Missing heart axis data.
			V5 (WEEK 36)	EVALUABLE		Rec. speed 25 mm/sec. Missing heart axis data.
			V6 (WEEK 52)	EVALUABLE		Rec. speed 25 mm/sec. Missing heart axis data.
	052	21	SCREENING	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent.
			V1 (WEEK 0)	NOT EVALUABLE	POOR RECORDING QUALITY	The recording speed 25 mm/sec. The data of heart axis are absent.
			V3 (WEEK 12)	NOT EVALUABLE	LEAD(S) NOT AVAILABLE	Leads V2, V5, V4 are missing. Heart axis is missing. Speed 25 mm/s. No overall conclusion. Lead II measureable.

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	052	21	V4 (WEEK 24)	11APR2011	57	175	83	446	450	449	983	NORMAL VARIANT
			V5 (WEEK 36)	04JUL2011	61	172	85	433	445	441	944	NORMAL VARIANT
			V6 (WEEK 52)	24OCT2011	68	151	85	405	441	429	846	NORMAL VARIANT
	055	5	SCREENING	08MAR2010	48	171	86	475	417	435	1296	NORMAL VARIANT
			V1 (WEEK 0)	29MAR2010	58	148	86	422	419	420	1012	NORMAL VARIANT
			V6 (WEEK 52)	27APR2010	65	136	87	407	429	421	903	NORMAL
	057	1	SCREENING	29JUL2010	59	154	92	410	421	417	952	NORMAL VARIANT
			V1 (WEEK 0)	19AUG2010	55	155	92	414	399	404	1077	NORMAL VARIANT
			V3 (WEEK 12)	08NOV2010	62	159	94	390	368	375	1123	NORMAL VARIANT
			V4 (WEEK 24)	04FEB2011	57	155	95	402	398	399	1019	NORMAL VARIANT
	066	16	SCREENING	09AUG2010	54	226	89	427	414	418	1063	ABNORMAL
			V1 (WEEK 0)	09SEP2010	67	220	89	399	428	418	866	ABNORMAL
			V3 (WEEK 12)	30NOV2010		220	91	430	424	427	1046	ABNORMAL
	067	16	SCREENING	02NOV2010	79	136	78	356	412	393	746	NORMAL VARIANT
			V1 (WEEK 0)	18NOV2010	67	160	75	373	399	390	876	NORMAL
			V6 (WEEK 52)	25JAN2011	72	144	73	359	396	383	827	NORMAL VARIANT

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	052	21	V4 (WEEK 24)	EVALUABLE		Rec. speed 25 mm/sec. Missing heart axis data.
			V5 (WEEK 36)	EVALUABLE		Rec. speed 25 mm/sec. Missing heart axis data.
			V6 (WEEK 52)	EVALUABLE		Rec. speed 25 mm/sec. Missing heart axis data.
	055	5	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	057	1	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
	066	16	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
	067	16	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	071	18	SCREENING	20OCT2010	53	190	84	443	422	429	1104	NORMAL VARIANT
			V1 (WEEK 0)	09NOV2010	55	168	83	432	415	421	1084	NORMAL VARIANT
			V3 (WEEK 12)	03FEB2011	58	166	87	425	418	421	1034	NORMAL VARIANT
			V4 (WEEK 24)	04MAY2011	50	173	88	447	414	424	1167	NORMAL VARIANT
			V5 (WEEK 36)	19JUL2011	60	162	87	437	438	437	993	NORMAL
			V6 (WEEK 52)	17NOV2011	60	168	89	421	422	422	996	NORMAL
	080	13	SCREENING	08NOV2010	65	165	91	384	399	394	928	NORMAL VARIANT
			UNSCHEDULED	01JUN2011	54	165	97	431	414	419	1085	NORMAL VARIANT
			V1 (WEEK 0)	18NOV2010	80	166	90	369	428	407	745	NORMAL VARIANT
			V3 (WEEK 12)	09FEB2011	65	173	91	384	398	393	931	NORMAL VARIANT
	081	17	SCREENING	04OCT2010	65	195	161	441	452	449	953	ABNORMAL
			V1 (WEEK 0)	14OCT2010	65	199	157	420	433	429	944	ABNORMAL
			V3 (WEEK 12)	10JAN2011	67	195	161	422	439	434	925	ABNORMAL
			V4 (WEEK 24)	06APR2011	78	156	92	375	427	409	773	NORMAL VARIANT
			V5 (WEEK 36)	20JUN2011	67	197	152	419	440	433	909	ABNORMAL
			V6 (WEEK 52)	24OCT2011	63	212	154	417	432	427	931	ABNORMAL

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	071	18	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		Speed 25 mm/s
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	080	13	SCREENING	EVALUABLE		The recording speed 25 mm/sec.
			UNSCHEDULED	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
	081	17	SCREENING	EVALUABLE		Heart axis missing
			V1 (WEEK 0)	EVALUABLE		Heart axis missing
			V3 (WEEK 12)	EVALUABLE		Heart axis missing
			V4 (WEEK 24)	EVALUABLE		The data of the heart axis are missing. Wrong measurements and interpretation are possible, because the quality of ECG recording is insufficient.
			V5 (WEEK 36)	EVALUABLE		Heart axis missing.
			V6 (WEEK 52)	EVALUABLE		Missing heart axis data.

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	083	17	SCREENING	26OCT2010	67	138	89	391	424	413	851	NORMAL
			V1 (WEEK 0)	10NOV2010	64	169	92	370	385	380	927	NORMAL
			V4 (WEEK 24)	26APR2011		175	85	427	436	433	963	NORMAL VARIANT
			V6 (WEEK 52)	09NOV2011	58	172	97	396	387	389	1048	NORMAL VARIANT
	087	16	SCREENING	09NOV2010	65	199	92	376	395	388	907	NORMAL VARIANT
			V1 (WEEK 0)	29NOV2010	67	182	98	391	413	406	896	NORMAL VARIANT
			V3 (WEEK 12)	17FEB2011	66	202	87	359	382	374	884	NORMAL VARIANT
			V4 (WEEK 24)	16MAY2011	70	193	85	360	395	384	832	NORMAL VARIANT
			V5 (WEEK 36)	10AUG2011	68	197	93	350	380	370	849	NORMAL VARIANT
			V6 (WEEK 52)	28NOV2011	61	193	88	396	403	400	967	NORMAL VARIANT
	089	5	SCREENING	19OCT2010	55	207	87	448	434	439	1063	NORMAL VARIANT
			V1 (WEEK 0)	16NOV2010	59	200	84	420	419	419	1003	NORMAL VARIANT
			V3 (WEEK 12)	07FEB2011	61	207	83	410	420	417	954	NORMAL VARIANT
			V4 (WEEK 24)	02MAY2011	53	195	84	424	400	408	1124	NORMAL VARIANT
			V5 (WEEK 36)	25JUL2011	59	205	84	423	416	418	1031	NORMAL VARIANT
			V6 (WEEK 52)	14NOV2011	54	203	78	450	436	441	1066	NORMAL VARIANT

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	083	17	SCREENING	EVALUABLE		Heart axis missing. Limb leads: insufficient quality.
			V1 (WEEK 0)	EVALUABLE		Heart axis missing
			V4 (WEEK 24)	EVALUABLE		The data of the heart axis are missing
			V6 (WEEK 52)	EVALUABLE		Missing heart axis data.
	087	16	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	089	5	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
ACI-91	093	17	SCREENING	29NOV2010	90	154	95	317	395	367	643	NORMAL
			V1 (WEEK 0)	02DEC2010	97	137	95	329	416	385	625	NORMAL VARIANT
			V3 (WEEK 12)	25FEB2011	98	142	92	314	409	375	592	NORMAL VARIANT
			V4 (WEEK 24)	23MAY2011	70	191	141	402	440	427	835	ABNORMAL
			V6 (WEEK 52)	06DEC2011	60	151	91	368	373	372	970	NORMAL VARIANT
	097	12	SCREENING	27OCT2010	66	132	97	330	348	342	901	NORMAL
			V1 (WEEK 0)	17NOV2010	66	132	101	309	320	317	950	ABNORMAL
			V3 (WEEK 12)	09FEB2011	76	149	96	307	352	337	761	ABNORMAL
Placebo	001	1	SCREENING	02APR2009	75	184	132	450	508	488	783	ABNORMAL
			V1 (WEEK 0)	09APR2009	73	188	158	457	525	501	760	ABNORMAL
			V3 (WEEK 12)	07JUL2009	75	208	139	437	481	466	824	ABNORMAL
			V4 (WEEK 24)	17SEP2009	68	151	103	439	471	460	870	ABNORMAL
			V5 (WEEK 36)	10DEC2009	66	155	105	435	458	450	902	NORMAL
			V6 (WEEK 52)	08APR2010	61	172	108	442	447	445	981	NORMAL
	003	1	SCREENING	07MAY2009	62	177	74	372	406	398	888	NORMAL VARIANT
			V1 (WEEK 0)	28MAY2009	58	180	84	402	401	404	1047	NORMAL VARIANT
			V3 (WEEK 12)	25AUG2009	66	188	84	385	406	399	898	NORMAL VARIANT
			V4 (WEEK 24)	12NOV2009	61	181	85	390	400	397	954	NORMAL VARIANT

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
ACI-91	093	17	SCREENING	EVALUABLE		Heart axis missing.
			V1 (WEEK 0)	EVALUABLE		Heart axis missing. Limb leads: insufficient quality.
			V3 (WEEK 12)	EVALUABLE		Heart axis missing. Limb leads: insufficient quality.
			V4 (WEEK 24)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		Missing heart axis data.
	097	12	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
Placebo	001	1	SCREENING	EVALUABLE		25 mm/sec. recording speed
			V1 (WEEK 0)	EVALUABLE		25 mm/sec. recording speed
			V3 (WEEK 12)			
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
	003	1	SCREENING	NOT EVALUABLE	OTHER	25 mm/sec. recording speed
			V1 (WEEK 0)	NOT EVALUABLE	OTHER	25 mm/sec. recording speed
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	005	2	SCREENING	15MAY2009	54	173	91	408	390	396	1096	NORMAL VARIANT
			V1 (WEEK 0)	04JUN2009	55	174	91	391	375	381	1086	NORMAL VARIANT
			V3 (WEEK 12)	25AUG2009	51	192	92	416	385	396	1167	NORMAL VARIANT
			V4 (WEEK 24)	18NOV2009	50	194	89	428	398	408	1163	NORMAL VARIANT
			V5 (WEEK 36)	16FEB2010	53	183	89	423	396	403	1099	NORMAL VARIANT
			V6 (WEEK 52)	02JUN2010	56	194	92	422	414	417	1037	NORMAL VARIANT
	009	1	SCREENING	06AUG2009	68	176	86	396	424	415	868	NORMAL
			V1 (WEEK 0)	08SEP2009	72	178	87	387	429	414	815	NORMAL
			V3 (WEEK 12)	10DEC2009	68	173	89	400	426	417	880	NORMAL
			V4 (WEEK 24)	04MAR2010	64	165	90	398	423	414	905	NORMAL
			V5 (WEEK 36)	11MAY2010	67	171	90	398	423	414	883	NORMAL
			V6 (WEEK 52)	03SEP2010	68	177	88	393	414	407	898	NORMAL
	011	1	SCREENING	05NOV2009	87	172	82	319	393	367	661	ABNORMAL
			V1 (WEEK 0)	26NOV2009	87	172	81	340	404	381	705	ABNORMAL
			V3 (WEEK 12)	18FEB2010	73	165	89	377	419	405	812	ABNORMAL
			V4 (WEEK 24)	06MAY2010	93	168	123	345	430	400	642	ABNORMAL
			V5 (WEEK 36)	05AUG2010	86		122	374	440	417	720	ABNORMAL
			V6 (WEEK 52)	26NOV2010	73		122	388	434	419	795	ABNORMAL
	013	4	SCREENING	17AUG2009	54	183	95	436	410	418	1133	NORMAL VARIANT
			V1 (WEEK 0)	16SEP2009	73	171	95	399	443	428	808	NORMAL

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	005	2	SCREENING	EVALUABLE		The recording speed is 25 mm/sec.
			V1 (WEEK 0)	EVALUABLE		The recording speed is 25 mm/sec.
			V3 (WEEK 12)	EVALUABLE		The recording speed is 25 mm/sec.
			V4 (WEEK 24)	EVALUABLE		The recording speed is 25 mm/sec.
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		The recording speed is 25 mm/sec.
	009	1	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	011	1	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	013	4	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	013	4	V3 (WEEK 12)	09DEC2009	64	175	95	420	441	434	908	NORMAL
			V4 (WEEK 24)	04MAR2010	68	172	95	427	429	429	992	NORMAL
			V5 (WEEK 36)	20MAY2010	61	172	94	435	441	439	974	NORMAL
			V6 (WEEK 52)	16SEP2010	64	184	95	412	425	421	945	NORMAL VARIANT
	016	4	SCREENING	01FEB2010	60	131	90	400	400	400	1002	NORMAL
			V1 (WEEK 0)	01MAR2010	59	135	90	437	426	430	1051	NORMAL
			V3 (WEEK 12)	19MAY2010	66	135	95	401	420	413	912	NORMAL VARIANT
			V4 (WEEK 24)	09AUG2010	54	131	90	403	389	394	1077	NORMAL VARIANT
			V5 (WEEK 36)	08NOV2010	64	125	90	390	410	403	902	NORMAL VARIANT
			V6 (WEEK 52)	28FEB2011	66	122	90	379	399	391	904	NORMAL VARIANT
	018	5	SCREENING	03NOV2009	54	176	89	456	425	435	1151	NORMAL VARIANT
			V1 (WEEK 0)	23NOV2009	58	180	83	422	415	418	1037	NORMAL VARIANT
			V3 (WEEK 12)	16FEB2010	58	177	76	411	402	405	1042	NORMAL VARIANT
			V4 (WEEK 24)	11MAY2010	58	181	83	414	406	409	1036	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	013	4	V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		No data of heart axis.
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		The data of the heart axis are missing.
	016	4	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	NOT EVALUABLE	REVERSAL LIMB LEADS	Heart axis absent. Incorrect cable connection: the left arm and right arm electrode cables are reversed. The intervals were measured in lead III (real lead II). The data of the heart axis are missing.
			V6 (WEEK 52)	NOT EVALUABLE	REVERSAL LIMB LEADS	The data of the heart axis are missing.
	018	5	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		The recording speed is 25 mm/sec.

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	018	5	V5 (WEEK 36)	27JUL2010	49	176	81	440	399	412	1214	NORMAL VARIANT
			V6 (WEEK 52)	23NOV2010	56	177	82	403	393	393	1056	NORMAL VARIANT
	020	5	SCREENING	27JAN2010	51	160	85	433	400	410	1175	NORMAL VARIANT
			V1 (WEEK 0)	22FEB2010	51	170	84	422	389	400	1179	NORMAL VARIANT
	024	4	SCREENING	16JUL2010	58	173	146	471	473	473	990	ABNORMAL
			V1 (WEEK 0)	16AUG2010	58	172	147	456	424	434	1157	ABNORMAL
			V3 (WEEK 12)	10NOV2010	64	170	144	429	443	439	939	ABNORMAL
			V4 (WEEK 24)	02FEB2011	61	172	143	449	453	452	981	ABNORMAL
			V5 (WEEK 36)	18APR2011	61	176	140	439	443	442	984	ABNORMAL
			V6 (WEEK 52)	08AUG2011	78	171	143	431	453	445	907	ABNORMAL
	028	20	SCREENING	18NOV2010	76	141	101	378	426	409	787	NORMAL
			V1 (WEEK 0)	26NOV2010	74	142	101	370	409	395	817	NORMAL
			V3 (WEEK 12)	22FEB2011	80	129	101	377	433	414	757	NORMAL VARIANT
			V4 (WEEK 24)	24AUG2011	94	145	100	350	428	400	669	NORMAL
			V5 (WEEK 36)	25AUG2011	85	123	101	369	441	416	699	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	018	5	V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	020	5	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
	024	4	SCREENING	EVALUABLE		Heart axis absent.
			V1 (WEEK 0)	EVALUABLE		Heart axis absent.
			V3 (WEEK 12)	EVALUABLE		The data of the heart axis are missing.
			V4 (WEEK 24)	EVALUABLE		The data of the heart axis are missing. Electronic oscillations (mush) on lead II: wrong results of measurement are possible.
			V5 (WEEK 36)	EVALUABLE		The data of the heart axis are missing.
			V6 (WEEK 52)	EVALUABLE		
	028	20	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	028	20	V6 (WEEK 52)	24NOV2011	74	147	102	389	430	415	818	NORMAL VARIANT
	029	8	SCREENING	26JAN2010	72	162	96	383	420	407	832	NORMAL
			V1 (WEEK 0)	29JAN2010	72	162	91	393	428	416	841	NORMAL
			V3 (WEEK 12)	20APR2010	65	165	96	376	395	389	908	NORMAL
			V4 (WEEK 24)	05JUL2010	65	163	95	385	411	402	881	NORMAL
			V5 (WEEK 36)	30SEP2010	64	164	94	393	403	400	952	NORMAL
			V6 (WEEK 52)	01FEB2011	67	170	92	366	393	384	867	NORMAL
	031	8	SCREENING	06MAY2010	56	181	82	403	389	394	1071	NORMAL VARIANT
			V1 (WEEK 0)	20MAY2010	70	180	84	378	409	399	854	NORMAL VARIANT
			V3 (WEEK 12)	17AUG2010	70	181	82	383	435	418	776	NORMAL VARIANT
			V4 (WEEK 24)	09NOV2010	80	184	83	376	407	396	852	NORMAL VARIANT
			V5 (WEEK 36)	25JAN2011	69	172	83	350	380	369	848	NORMAL VARIANT
			V6 (WEEK 52)	17MAY2011	63	175	87	388	405	400	915	NORMAL VARIANT
	034	9	SCREENING	24FEB2010	74	148	74	367	402	390	832	NORMAL VARIANT
			V1 (WEEK 0)	18MAR2010	71	149	72	369	403	391	839	NORMAL VARIANT
			V4 (WEEK 24)	08SEP2010	76	148	73	370	420	402	775	NORMAL VARIANT
			V5 (WEEK 36)	30NOV2010	71	149	73	381	417	404	834	NORMAL
			V6 (WEEK 52)	15MAR2011	79	150	71	381	441	420	748	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	028	20	V6 (WEEK 52)	EVALUABLE		
	029	8	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	031	8	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	034	9	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	041	12	SCREENING	23SEP2009	56	166	95	413	404	407	1048	NORMAL VARIANT
			V1 (WEEK 0)	09OCT2009	69	166	95	413	404	407	846	ABNORMAL
			V3 (WEEK 12)	05JAN2010	72	169	102	414	466	448	788	ABNORMAL
			V4 (WEEK 24)	24MAR2010	74	178	105	403	451	434	799	ABNORMAL
			V5 (WEEK 36)	16JUN2010	69	180	105	404	454	437	796	ABNORMAL
			V6 (WEEK 52)	06OCT2010	58	178	104	444	449	447	975	ABNORMAL
	044	12	SCREENING	04NOV2009	63	223	149	426	438	434	951	ABNORMAL
			V1 (WEEK 0)	02DEC2009	63	226	152	440	434	436	1025	ABNORMAL
			V3 (WEEK 12)	24FEB2010	65	216	157	429	454	446	891	ABNORMAL
			V4 (WEEK 24)	26MAY2010	65	213	161	441	460	454	917	ABNORMAL
			V5 (WEEK 36)	18AUG2010	81	180	163	410	468	448	768	ABNORMAL
			V6 (WEEK 52)	01DEC2010	69	211	165	450	484	473	865	ABNORMAL
	045	11	SCREENING	07DEC2009	60	151	110	419	424	422	976	NORMAL
			V1 (WEEK 0)	21DEC2009	56	149	110	415	403	407	1060	NORMAL VARIANT

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	041	12	SCREENING	EVALUABLE		The date of the heart axis are absent.
			V1 (WEEK 0)	EVALUABLE		The data of the heart axis are absent.
			V3 (WEEK 12)	EVALUABLE		The recording speed is 25 mm/sec.. The data of the heart axis are absent.
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	044	12	SCREENING	NOT EVALUABLE	OTHER	Incorrect cable connection
			V1 (WEEK 0)	EVALUABLE		The trace in lead II is bad quality. The intervals were measured in lead V5. The data of the heart axis are absent.
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	045	11	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	045	11	V3 (WEEK 12)	15MAR2010	59	152	109	417	413	414	1021	NORMAL VARIANT
			V4 (WEEK 24)	07JUN2010	56	152	110	408	394	399	1072	NORMAL VARIANT
			V5 (WEEK 36)	06SEP2010	60	152	110	391	399	396	959	NORMAL VARIANT
			V6 (WEEK 52)	15DEC2010	55	152	109	408	392	397	1085	NORMAL VARIANT
	047	11	SCREENING	12JUL2010	64	193	101	403	415	411	939	NORMAL
			V1 (WEEK 0)	02AUG2010	63	184	100	401	409	406	962	NORMAL
			V3 (WEEK 12)	20OCT2010	54	183	101	420	398	405	1112	NORMAL VARIANT
			V4 (WEEK 24)	10JAN2011	58	184	100	410	404	406	1036	NORMAL VARIANT
			V5 (WEEK 36)	12APR2011	65	186	112	400	421	414	902	NORMAL VARIANT
			V6 (WEEK 52)	27JUL2011	56	188	109	427	414	418	1064	NORMAL VARIANT
	049	21	SCREENING	06SEP2010	47	145	91	453	407	422	1239	NORMAL VARIANT
			V1 (WEEK 0)	27OCT2010	65	158	91	416	445	435	877	NORMAL
			V3 (WEEK 12)	18JAN2011	77	156	93	384	443	422	749	NORMAL
			V4 (WEEK 24)	12APR2011	65	164	92	397	424	415	878	NORMAL
			V5 (WEEK 36)	05JUL2011	65	158	99	387	421	410	844	NORMAL

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	045	11	V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	047	11	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		The recording speed - 25 mm/sec
	049	21	SCREENING	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent.
			V1 (WEEK 0)	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent.
			V3 (WEEK 12)	EVALUABLE		Heart axis missing. Speed 25 mm/s
			V4 (WEEK 24)	EVALUABLE		Rec. speed 25 mm/s. Missing heart axis data.
			V5 (WEEK 36)	EVALUABLE		Rec. speed 25 mm/s. Missing heart axis data.

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	051	21	SCREENING	06SEP2010	75	165	93	396	434	421	831	NORMAL VARIANT
			V1 (WEEK 0)	28OCT2010	62	149	94	397	409	405	942	NORMAL VARIANT
			V3 (WEEK 12)	01FEB2011	63							
			V4 (WEEK 24)	12APR2011	79	157	90	364	426	404	732	NORMAL VARIANT
			V5 (WEEK 36)	05JUL2011	63	162	95	431	434	433	986	NORMAL VARIANT
			V6 (WEEK 52)	25OCT2011	76	166	95	377	429	411	771	NORMAL VARIANT
	056	5	SCREENING	31MAR2010	54	164	88	400	380	386	1108	NORMAL VARIANT
			V1 (WEEK 0)	21APR2010	57	160	90	404	391	396	1067	NORMAL VARIANT
			V3 (WEEK 12)	13JUL2010	56	165	92	418	396	403	1113	NORMAL VARIANT
			V4 (WEEK 24)	05OCT2010	52	164	87	404	376	385	1156	NORMAL VARIANT
			V5 (WEEK 36)	04JAN2011	60	161	88	414	416	415	987	NORMAL VARIANT
			V6 (WEEK 52)	19APR2011	50	163	88	420	391	401	1153	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	051	21	SCREENING	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent.
			V1 (WEEK 0)	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent.
			V3 (WEEK 12)	NOT EVALUABLE	POOR RECORDING QUALITY	Insufficient quality of the ECG traces. Measurement, interpretation and overall conclusion impossible.
			V4 (WEEK 24)	EVALUABLE		Rec. speed 25 mm/sec. Missing heart axis data.
			V5 (WEEK 36)	EVALUABLE		Rec. speed 25 mm/s. Missing heart axis data.
			V6 (WEEK 52)	EVALUABLE		Rec. speed 25 mm/sec. Missing heart axis data.
	056	5	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		Waving isoelectric line in lead II: wrong results of measurement and interpretation are possible.

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	058	1	SCREENING	06DEC2010	63	170	97	400	406	404	972	NORMAL VARIANT
			V1 (WEEK 0)	27DEC2010	67	168	87	386	406	399	907	NORMAL
			V3 (WEEK 12)	29MAR2011	65	171	92	402	426	418	889	NORMAL VARIANT
			V6 (WEEK 52)	06DEC2011	66	144	91	400	433	422	853	NORMAL VARIANT
	059	1	SCREENING	27DEC2010	69	114	92	396	418	411	902	ABNORMAL
			V1 (WEEK 0)	29DEC2010	71	113	94	379	405	396	877	ABNORMAL
			V3 (WEEK 12)	31MAR2011	75	114	93	355	421	398	711	ABNORMAL
			V5 (WEEK 36)	08SEP2011	78	110	94	441	511	487	745	ABNORMAL
			V6 (WEEK 52)	08DEC2011	68	108	95	373	402	392	864	ABNORMAL
	065	16	SCREENING	10AUG2010	46	167	109	454	405	421	1262	NORMAL VARIANT
			V1 (WEEK 0)	30AUG2010	73	138	103	384	428	413	806	NORMAL VARIANT
			V3 (WEEK 12)	22NOV2010	43	165	104	449	386	406	1353	NORMAL VARIANT
			V4 (WEEK 24)	17JAN2011	48	161	104	493	446	461	1226	NORMAL VARIANT
	068	16	SCREENING	26OCT2010	46	173	91	425	375	391	1285	NORMAL VARIANT
			V1 (WEEK 0)	22NOV2010	45	169	91	422	370	387	1301	NORMAL VARIANT
			V3 (WEEK 12)	10FEB2011	50	178	92	411	379	390	1176	NORMAL VARIANT
			V4 (WEEK 24)	03MAY2011	56	178	92	374	370	371	1019	NORMAL VARIANT
			V5 (WEEK 36)	10AUG2011	55	167	92	402	391	395	1056	NORMAL VARIANT
			V6 (WEEK 52)	28NOV2011	64	174	91	388	410	402	896	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	058	1	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	059	1	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	065	16	SCREENING			
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		5 mm/mv
			V4 (WEEK 24)	EVALUABLE		
	068	16	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	069	23	SCREENING	24NOV2010	62	192	99	380	390	387	947	NORMAL VARIANT
			V3 (WEEK 12)	09MAR2011	62	189	98	381	396	391	925	NORMAL VARIANT
			V4 (WEEK 24)	19MAY2011	61	196	99	390	399	396	952	NORMAL VARIANT
			V5 (WEEK 36)	24AUG2011	58	175	101	405	425	418	909	NORMAL VARIANT
			V6 (WEEK 52)	14DEC2011	73	182	100	377	422	407	797	NORMAL VARIANT
	072	18	SCREENING	01DEC2010	50	107	99	485	445	458	1186	ABNORMAL
			V1 (WEEK 0)	21DEC2010	54	123	98	471	446	454	1117	ABNORMAL
			V3 (WEEK 12)	19MAR2011	48	132	97	464	407	424	1285	NORMAL VARIANT
			V4 (WEEK 24)	07JUN2011	50	142	96	454	426	436	1131	NORMAL VARIANT
			V5 (WEEK 36)	08SEP2011	55	114	97	454	429	437	1119	NORMAL VARIANT
			V6 (WEEK 52)	15DEC2011	50	129	99	467	433	444	1163	NORMAL VARIANT
	079	13	SCREENING	19JUL2010	47	165	80	446	395	411	1274	
			UNSCHEDULED	19JUL2011	48	164	75	440	395	409	1246	NORMAL VARIANT
			V1 (WEEK 0)	06AUG2010	58	157	79	423	431	428	964	NORMAL VARIANT
			V3 (WEEK 12)	09NOV2010	51	146	82	425	395	405	1161	NORMAL VARIANT
			V4 (WEEK 24)	27JAN2011	47	163	74	444	398	412	1246	NORMAL VARIANT

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	069	23	SCREENING	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	072	18	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		ND = not done
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	079	13	SCREENING		REVERSAL LIMB LEADS	25 mm/s. recording speed. Due to reversal left arm and right leg electrodes, no overall conclusion and interpretation available.
			UNSCHEDULED	NOT EVALUABLE	LEAD(S) NOT AVAILABLE	Precordial leads are missing: uncorrect interpretation is possible.
			V1 (WEEK 0)			25 mm/s. recording speed.
			V3 (WEEK 12)	EVALUABLE		THE RECORDING SPEED 25 MM/SEC.
			V4 (WEEK 24)	EVALUABLE		

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	079	13	V5 (WEEK 36)	11APR2011	53	144	81	390	370	376	1112	NORMAL VARIANT
			V6 (WEEK 52)	21JUN2011	62	173	75	405	420	415	929	NORMAL
	082	17	SCREENING	06OCT2010	58	183	99	365	365	365	1002	NORMAL VARIANT
			V1 (WEEK 0)	14OCT2010	66	185	99	356	371	366	944	NORMAL VARIANT
			V3 (WEEK 12)	05JAN2011	65	200	102	372	382	378	948	NORMAL VARIANT
			V4 (WEEK 24)	06APR2011	62	186	100	374	381	379	964	NORMAL VARIANT
			V5 (WEEK 36)	22JUN2011	58	185	99	360	357	358	1013	NORMAL VARIANT
			V6 (WEEK 52)	12OCT2011	64	200	100	368	389	382	897	NORMAL VARIANT
			SCREENING	08NOV2010	71	186	93	365	404	390	816	NORMAL VARIANT
			V1 (WEEK 0)	17NOV2010	69	178	90	372	402	392	853	NORMAL
	084	17	V3 (WEEK 12)	08FEB2011	65	182	90	392	401	398	960	NORMAL
			V4 (WEEK 24)	10MAY2011	72	172	85	382	408	399	874	NORMAL VARIANT
			V5 (WEEK 36)	02AUG2011	61	154	88	410	414	413	980	NORMAL VARIANT
			V6 (WEEK 52)	22NOV2011	53	181	87	439	405	413	1133	NORMAL VARIANT
			SCREENING	04OCT2010	76	143	92	437	444	441	742	ABNORMAL

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	079	13	V5 (WEEK 36) V6 (WEEK 52)	EVALUABLE EVALUABLE		Waving isoelectric line in most part of limb leads: wrong interpretation is possible.
	082	17	SCREENING V1 (WEEK 0) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52)	EVALUABLE EVALUABLE EVALUABLE EVALUABLE EVALUABLE EVALUABLE		Heart axis missing Heart axis missing Heart axis missing The data of the heart axis are missing. Missing heart axis data. Missing heart axis data.
	084	17	SCREENING V1 (WEEK 0) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52)	EVALUABLE EVALUABLE EVALUABLE EVALUABLE EVALUABLE		Heart axis missing Heart axis missing Heart axis missing Missing heart axis data. Missing heart axis data.
	086	21	SCREENING	NOT EVALUABLE	POOR RECORDING QUALITY	The recording speed 25 mm/sec. The data of heart axis are absent.

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	Date	Heart rate [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]	Overall conclusion
Placebo	086	21	V1 (WEEK 0)	28OCT2010	58	148	92	437	443	441	972	NORMAL VARIANT
			V3 (WEEK 12)	18JAN2011	58	156	90	406	435	425	871	NORMAL VARIANT
			V4 (WEEK 24)	12APR2011	59	159	85	397	428	417	864	NORMAL VARIANT
			V5 (WEEK 36)	05JUL2011	71	174	88	369	411	397	807	NORMAL VARIANT
			V6 (WEEK 52)	25OCT2011	64	160	98	427	449	442	902	NORMAL VARIANT
	088	16	SCREENING	30NOV2010	72	125	81	358	391	380	836	NORMAL
			V1 (WEEK 0)	09DEC2010	66	114	84	400	428	418	876	NORMAL VARIANT
			V3 (WEEK 12)	01MAR2011	72	121	74	355	395	381	807	NORMAL VARIANT
			V4 (WEEK 24)	19MAY2011	70	114	74	376	407	396	857	NORMAL VARIANT
			V5 (WEEK 36)	29AUG2011	64	115	85	395	415	408	906	NORMAL VARIANT

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Treat- ment	Random No.	Site ID	Visit	ECG Quality#	Reason, for not evaluable	Comment
Placebo	086	21	V1 (WEEK 0)	EVALUABLE		The recording speed 25 mm/sec. The data of heart axis are absent. Heart axis is missing. Speed 25 mm/s Rec. speed 25 mm/sec. Missing heart axis data. Rec. speed 25 mm/s. Missing heart axis data. Rec. speed 25 mm/s. Missing heart axis data.
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		
			V6 (WEEK 52)	EVALUABLE		
	088	16	SCREENING	EVALUABLE		
			V1 (WEEK 0)	EVALUABLE		
			V3 (WEEK 12)	EVALUABLE		
			V4 (WEEK 24)	EVALUABLE		
			V5 (WEEK 36)	EVALUABLE		

Values/interpretation of ECGs with quality = 'Not evaluable' were excluded from descriptive statistics and figures
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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	002	1	SCREENING	02APR2009	Normal T wave in lead II Normal sinus rhythm Short PR interval	Limb leads
			V1 (WEEK 0)	23APR2009	Normal T wave in lead II Short PR interval Sinus bradycardia	
			V3 (WEEK 12)	16JUL2009	Atrial ectopic pacemaker Low voltage of QRS complex in Non specific P wave abnormality Normal T wave in lead II Short PR interval	
			V4 (WEEK 24)	08OCT2009	Atrial ectopic pacemaker Non specific P wave abnormality Normal T wave in lead II Short PR interval	
			V5 (WEEK 36)	05JAN2010	Normal T wave in lead II Normal sinus rhythm Short PR interval T-U waves fusion in	
			V6 (WEEK 52)	22APR2010	Junctional tachycardia Left atrial abnormality Normal T wave in lead II Short PR interval	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	004	1	SCREENING	17JUN2009	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	16JUL2009	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	15OCT2009	Normal T wave in lead II Normal sinus rhythm	
	006	2	V3 (WEEK 12)	21MAY2010	Isolated atrial premature complex(es) Isolated ventricular premature complex(es), monomorphic	
			V4 (WEEK 24)	13AUG2010	Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	04NOV2010	Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	24FEB2011	Normal T wave in lead II Wandering atrial pacemaker	
	010	1	SCREENING	26JUN2009	Intraventricular conduction disturbance, nonspecific type Left axis deviation Sinus bradycardia	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	010	1	SCREENING	26JUN2009	T wave morphology in lead II: diphasic (positive-negative)	
			V1 (WEEK 0)	21JUL2009	Intraventricular conduction disturbance, nonspecific type Left axis deviation Sinus bradycardia	
			V3 (WEEK 12)	13OCT2009	T wave morphology in lead II: diphasic (positive-negative) Intraventricular conduction disturbance, nonspecific type Left axis deviation Normal T wave in lead II Sinus bradycardia	
	012	1	SCREENING	17JUN2010	Complete RBBB Left anterior fascicular block Left axis deviation Misplaced precordial electrode(s) Sinus bradycardia	
			UNSCHEDULED	18AUG2011	T wave morphology in lead II: low Left axis deviation Normal T wave in lead II Sinus bradycardia	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	012	1	V1 (WEEK 0)	19JUL2010	Complete RBBB Left anterior fascicular block Left axis deviation Sinus bradycardia T wave morphology in lead II: low	
			V3 (WEEK 12)	14OCT2010	Complete RBBB Left anterior fascicular block Left axis deviation Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	10JAN2011	Complete RBBB Left anterior fascicular block Left axis deviation Normal T wave in lead II Sinus bradycardia	
			V5 (WEEK 36)	01APR2011	Complete RBBB Left anterior fascicular block Left axis deviation Normal T wave in lead II Sinus bradycardia	
	014	4	SCREENING	07OCT2009	Normal sinus rhythm T wave morphology in lead II: flat	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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13FEB2013

Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	014	4	V1 (WEEK 0)	02NOV2009	Sinus bradycardia	
					T wave morphology in lead II: flat	
			V3 (WEEK 12)	25JAN2010	Sinus bradycardia	
					T wave morphology in lead II: flat	
			V4 (WEEK 24)	22APR2010	Normal sinus rhythm	
					T wave morphology in lead II: flat	
	015	4	V5 (WEEK 36)	15JUL2010	Sinus bradycardia	
					T wave morphology in lead II: flat	
			V6 (WEEK 52)	28OCT2010	Sinus bradycardia	
					T wave morphology in lead II: flat	
			SCREENING	21JAN2010	Normal T wave in lead II	
					Sinus bradycardia	
			V1 (WEEK 0)	22FEB2010	Normal T wave in lead II	
					Sinus bradycardia	
			V3 (WEEK 12)	17MAY2010	Normal T wave in lead II	
					Sinus bradycardia	
			V4 (WEEK 24)	02AUG2010	Normal T wave in lead II	
					Sinus bradycardia	
			V5 (WEEK 36)	27OCT2010	Normal T wave in lead II	
					Sinus bradycardia	
			V6 (WEEK 52)	21FEB2011	Misplaced precordial electrode(s)	
					Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	015	4	V6 (WEEK 52)	21FEB2011	Sinus bradycardia	
	017	5	SCREENING	14JUL2009	Normal sinus rhythm T wave morphology in lead II: diphasic (negative-positive)	
			V1 (WEEK 0)	05AUG2009	Normal sinus rhythm T wave morphology in lead II: low	
			V3 (WEEK 12)	28OCT2009	Normal sinus rhythm T wave morphology in lead II: low	
			V4 (WEEK 24)	20JAN2010	Normal sinus rhythm T wave morphology in lead II: low	
			V5 (WEEK 36)	13APR2010	Isolated ventricular premature complex(es), monomorphic Normal sinus rhythm T wave morphology in lead II: low	
	019	5	SCREENING	18NOV2009	First degree AV block Non specific P wave abnormality Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	09DEC2009	First degree AV block Non specific P wave abnormality Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	019	5	V1 (WEEK 0)	09DEC2009	Normal sinus rhythm	
			V3 (WEEK 12)	03MAR2010	First degree AV block Non specific P wave abnormality Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	25MAY2010	First degree AV block Intraventricular conduction disturbance, nonspecific type Isolated ventricular premature complex(es), monomorphic Non specific P wave abnormality Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	24AUG2010	Non specific P wave abnormality Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	07DEC2010	Poor R wave progression in precordial leads First degree AV block Intraventricular conduction disturbance, nonspecific type Isolated ventricular premature complex(es), monomorphic Non specific P wave abnormality	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	019	5	V6 (WEEK 52)	07DEC2010	Normal T wave in lead II Normal sinus rhythm	
	023	4	SCREENING	01JUL2010	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	20JUL2010	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	13OCT2010	T-U waves fusion in Normal T wave in lead II Normal sinus rhythm	Other localization
			V4 (WEEK 24)	12JAN2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	21MAR2011	Isolated atrial premature complex(es) Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	18JUL2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm T-U waves fusion in	Anterior leads / Inferior leads

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	027	20	SCREENING	30SEP2010	Atrial ectopic pacemaker Low voltage of QRS complex in Normal T wave in lead II	Limb leads
			V1 (WEEK 0)	21OCT2010	Atrial ectopic pacemaker Low voltage of QRS complex in Normal T wave in lead II	Limb leads
			V3 (WEEK 12)	20JAN2011	Atrial ectopic pacemaker Low voltage of QRS complex in Normal T wave in lead II	Limb leads
			V4 (WEEK 24)	12APR2011	Low voltage of QRS complex in Non specific ST or T wave abnormalities Normal T wave in lead II Normal sinus rhythm	Limb leads
			V5 (WEEK 36)	06JUN2011	Low voltage of QRS complex in Non specific ST or T wave abnormalities Normal T wave in lead II Normal sinus rhythm	Limb leads
			V6 (WEEK 52)	25OCT2011	Low voltage of QRS complex in Non specific ST or T wave abnormalities Normal T wave in lead II Normal sinus rhythm	Limb leads
	030	8	SCREENING	18MAR2010	Isolated atrial premature complex(es)	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	030	8	SCREENING	18MAR2010	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	25MAR2010	Atrial ectopic pacemaker Non specific P wave abnormality	
			V3 (WEEK 12)	17JUN2010	Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	03SEP2010	Normal T wave in lead II Sinus bradycardia	
			V5 (WEEK 36)	02DEC2010	Normal T wave in lead II Sinus bradycardia	
			V6 (WEEK 52)	14MAR2011	Normal T wave in lead II Sinus bradycardia	
	032	8	SCREENING	08NOV2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	18NOV2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	032	8	V3 (WEEK 12)	07FEB2011	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	
	033	9	SCREENING	28OCT2009	Normal sinus rhythm T wave morphology in lead II: diphasic (negative-positive)	
			V1 (WEEK 0)	04NOV2009	Atrial ectopic pacemaker Non specific P wave abnormality Normal T wave in lead II	
			V3 (WEEK 12)	20JAN2010	Isolated ventricular premature complex(es), monomorphic Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	21APR2010	Normal T wave in lead II Sinus bradycardia	
			V6 (WEEK 52)	10NOV2010	Normal T wave in lead II Normal sinus rhythm	
	042	12	SCREENING	16DEC2009	Normal sinus rhythm	
			V1 (WEEK 0)	14JAN2010	Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	042	12	V1 (WEEK 0)	14JAN2010	Short PR interval	
			V3 (WEEK 12)	14MAY2010	Normal T wave in lead II Normal sinus rhythm Short PR interval	
			V4 (WEEK 24)	30JUN2010	Normal T wave in lead II Normal sinus rhythm Short PR interval	
			V5 (WEEK 36)	22SEP2010	Normal T wave in lead II Normal sinus rhythm Short PR interval	
			V6 (WEEK 52)	12JAN2011	Normal T wave in lead II Normal sinus rhythm Short PR interval	
	043	12	SCREENING	21OCT2009	Complete RBBB Infarction, age undetermined in Left posterior fascicular block Normal sinus rhythm T wave morphology in lead II: diphasic (negative-positive)	Inferior leads
			V1 (WEEK 0)	18NOV2009	Complete RBBB Infarction, age undetermined in	Inferior leads

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	043	12	V1 (WEEK 0)	18NOV2009	Isolated ventricular premature complex(es), monomorphic Left posterior fascicular block Normal sinus rhythm T wave morphology in lead II: diphasic (negative-positive)	
			V3 (WEEK 12)	10FEB2010	Infarction, age undetermined in Intraventricular conduction disturbance, nonspecific type Isolated ventricular premature complex(es), monomorphic Non specific P wave abnormality Normal T wave in lead II Right axis deviation Wandering atrial pacemaker	Inferior leads / Other localization
			V4 (WEEK 24)	12MAY2010	Infarction, age undetermined in Intraventricular conduction disturbance, nonspecific type Isolated ventricular premature complex(es), monomorphic Non specific P wave abnormality	Inferior leads / Other localization

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	043	12	V4 (WEEK 24)	12MAY2010	Normal T wave in lead II Right axis deviation Wandering atrial pacemaker	
	046	11	SCREENING	14DEC2009	Borderline first degree AV block Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	11JAN2010	Borderline first degree AV block Isolated ventricular premature complex(es), polymorphic Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	07APR2010	First degree AV block Normal sinus rhythm	
			V4 (WEEK 24)	07JUL2010	First degree AV block Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	22SEP2010	First degree AV block Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	12JAN2011	First degree AV block Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	048	11	SCREENING	17NOV2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	22NOV2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	15FEB2011	Early repolarisation pattern Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	16MAY2011	Early repolarisation pattern Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	
			V5 (WEEK 36)	26JUL2011	Early repolarisation pattern Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	048	11	V6 (WEEK 52)	16NOV2011	Early repolarisation pattern Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	
	050	21	SCREENING	06SEP2010	Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads Sinus bradycardia	
			V1 (WEEK 0)	27OCT2010	Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads Sinus bradycardia	
			V3 (WEEK 12)	17JAN2011	Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads Sinus bradycardia	
			V4 (WEEK 24)	11APR2011	Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads Sinus bradycardia	
			V5 (WEEK 36)	04JUL2011	Misplaced precordial electrode(s)	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	050	21	V5 (WEEK 36)	04JUL2011	Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	
			V6 (WEEK 52)	04OCT2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	
	052	21	SCREENING	06SEP2010	Atrial ectopic pacemaker Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads	
			V1 (WEEK 0)	28OCT2010	Atrial ectopic pacemaker Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads	
			V3 (WEEK 12)	17JAN2011	Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	11APR2011	Atrial ectopic pacemaker Normal T wave in lead II	
			V5 (WEEK 36)	04JUL2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	052	21	V5 (WEEK 36)	04JUL2011	Poor R wave progression in precordial leads	
			V6 (WEEK 52)	24OCT2011	Atrial ectopic pacemaker Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads	
	055	5	SCREENING	08MAR2010	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	29MAR2010	Normal T wave in lead II Sinus bradycardia	
			V6 (WEEK 52)	27APR2010	Normal T wave in lead II Normal sinus rhythm	
	057	1	SCREENING	29JUL2010	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	19AUG2010	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	08NOV2010	Normal T wave in lead II Wandering atrial pacemaker	
			V4 (WEEK 24)	04FEB2011	Normal T wave in lead II Sinus bradycardia	
	066	16	SCREENING	09AUG2010	Atrial ectopic pacemaker	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	066	16	SCREENING	09AUG2010	First degree AV block	
					Normal T wave in lead II	
			V1 (WEEK 0)	09SEP2010	Atrial ectopic pacemaker	
	067	16			First degree AV block	
					Normal T wave in lead II	
			V3 (WEEK 12)	30NOV2010	First degree AV block	
					Normal T wave in lead II	
					Sinus bradycardia	
			SCREENING	02NOV2010	Misplaced precordial electrode(s)	
					Normal T wave in lead II	
					Normal sinus rhythm	
			V1 (WEEK 0)	18NOV2010	Normal T wave in lead II	
					Normal sinus rhythm	
			V6 (WEEK 52)	25JAN2011	Normal T wave in lead II	
					Wandering atrial pacemaker	
	071	18	SCREENING	20OCT2010	Normal T wave in lead II	
					Sinus bradycardia	
			V1 (WEEK 0)	09NOV2010	Normal T wave in lead II	
					Sinus bradycardia	
			V3 (WEEK 12)	03FEB2011	Atrial ectopic pacemaker	
					Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	071	18	V4 (WEEK 24)	04MAY2011	Normal T wave in lead II Sinus bradycardia	
			V5 (WEEK 36)	19JUL2011	Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	17NOV2011	Normal T wave in lead II Normal sinus rhythm	
	080	13	SCREENING	08NOV2010	Non specific P wave abnormality Normal T wave in lead II Normal sinus rhythm	
			UNSCHEDULED	01JUN2011	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	18NOV2010	Non specific P wave abnormality Normal T wave in lead II Normal sinus rhythm	
		17	V3 (WEEK 12)	09FEB2011	Non specific P wave abnormality Normal T wave in lead II Normal sinus rhythm	
			SCREENING	04OCT2010	Complete LBBB Normal T wave in lead II Normal sinus rhythm	
	081	17	V1 (WEEK 0)	14OCT2010	Complete LBBB	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	081	17	V1 (WEEK 0)	14OCT2010	Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	10JAN2011	Complete LBBB Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	06APR2011	Junctional escape complex(es) Misplaced precordial electrode(s) Normal sinus rhythm T wave morphology in lead II: low	
			V5 (WEEK 36)	20JUN2011	Complete LBBB Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	24OCT2011	Complete LBBB Normal T wave in lead II Normal sinus rhythm	
	083	17	SCREENING	26OCT2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	10NOV2010	Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	26APR2011	Atrial ectopic pacemaker Normal T wave in lead II	
			V6 (WEEK 52)	09NOV2011	Isolated atrial premature complex(es)	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	083	17	V6 (WEEK 52)	09NOV2011	Normal T wave in lead II Poor R wave progression in precordial leads Sinus bradycardia	
	087	16	SCREENING	09NOV2010	Normal T wave in lead II Normal sinus rhythm RSR pattern in lead V1	
			V1 (WEEK 0)	29NOV2010	Normal sinus rhythm RSR pattern in lead V1	
			V3 (WEEK 12)	17FEB2011	T wave morphology in lead II: low Borderline first degree AV block Non specific ST or T wave abnormalities Normal sinus rhythm RSR pattern in lead V1	
			V4 (WEEK 24)	16MAY2011	T wave morphology in lead II: low Non specific ST or T wave abnormalities Normal sinus rhythm RSR pattern in lead V1	
			V5 (WEEK 36)	10AUG2011	T wave morphology in lead II: low Non specific ST or T wave abnormalities Normal sinus rhythm RSR pattern in lead V1 T wave morphology in lead II: low	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	087	16	V6 (WEEK 52)	28NOV2011	Non specific ST or T wave abnormalities	
					Normal sinus rhythm	
					RSR pattern in lead V1	
					T wave morphology in lead II: low	
	089	5	SCREENING	19OCT2010	First degree AV block	
					Normal T wave in lead II	
					Sinus bradycardia	
			V1 (WEEK 0)	16NOV2010	Borderline first degree AV block	
					Normal T wave in lead II	
					Sinus bradycardia	
			V3 (WEEK 12)	07FEB2011	First degree AV block	
					Normal T wave in lead II	
		Wandering atrial pacemaker				
V4 (WEEK 24)	02MAY2011	Normal T wave in lead II				
		Sinus bradycardia				
V5 (WEEK 36)	25JUL2011	First degree AV block				
		Normal T wave in lead II				
		Wandering atrial pacemaker				
V6 (WEEK 52)	14NOV2011	First degree AV block				
		Normal T wave in lead II				
		Sinus bradycardia				

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	093	17	SCREENING	29NOV2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	02DEC2010	Normal T wave in lead II Wandering atrial pacemaker	
			V3 (WEEK 12)	25FEB2011	Normal T wave in lead II Wandering atrial pacemaker	
			V4 (WEEK 24)	23MAY2011	Complete LBBB Left axis deviation Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	06DEC2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	
	097	12	SCREENING	27OCT2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	17NOV2010	Isolated atrial premature complex(es) Isolated ventricular premature complex(es), monomorphic Junctional escape complex(es) Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
ACI-91	097	12	V3 (WEEK 12)	09FEB2011	Couplet ventricular premature complex(es) Isolated ventricular premature complex(es), monomorphic Normal T wave in lead II Normal sinus rhythm	
Placebo	001	1	SCREENING	02APR2009	Abnormal ST pattern in Complete LBBB Left axis deviation Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	Antero-septal leads
			V1 (WEEK 0)	09APR2009	Abnormal ST pattern in Complete LBBB Left axis deviation Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	Antero-septal leads
			V3 (WEEK 12)	07JUL2009	Abnormal ST pattern in Complete LBBB First degree AV block Left axis deviation Normal T wave in lead II	Antero-septal leads

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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13FEB2013

Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	001	1	V3 (WEEK 12)	07JUL2009	Normal sinus rhythm Poor R wave progression in precordial leads	
			V4 (WEEK 24)	17SEP2009	Normal sinus rhythm T wave morphology in lead II: flat	
			V5 (WEEK 36)	10DEC2009	Normal sinus rhythm T wave morphology in lead II: flat	
			V6 (WEEK 52)	08APR2010	Normal sinus rhythm T wave morphology in lead II: low	
	003	1	SCREENING	07MAY2009	Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	
			V1 (WEEK 0)	28MAY2009	Normal T wave in lead II Poor R wave progression in precordial leads Sinus bradycardia	
			V3 (WEEK 12)	25AUG2009	Atrial ectopic pacemaker Misplaced precordial electrode(s) Non specific P wave abnormality Normal T wave in lead II Poor R wave progression in precordial leads	
			V4 (WEEK 24)	12NOV2009	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	003	1	V4 (WEEK 24)	12NOV2009	Poor R wave progression in precordial leads	
	005	2	SCREENING	15MAY2009	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	04JUN2009	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	25AUG2009	Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	18NOV2009	Normal T wave in lead II Sinus bradycardia	
			V5 (WEEK 36)	16FEB2010	Normal T wave in lead II Right atrial abnormality Sinus bradycardia	
			V6 (WEEK 52)	02JUN2010	Normal T wave in lead II Sinus bradycardia	
	009	1	SCREENING	06AUG2009	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	08SEP2009	Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	10DEC2009	Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	04MAR2010	Infarction, age undetermined in	Other localization

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	009	1	V4 (WEEK 24)	04MAR2010	Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	11MAY2010	Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	03SEP2010	Normal T wave in lead II Normal sinus rhythm	
	011	1	SCREENING	05NOV2009	Infarction, age undetermined in Low voltage of QRS complex in Normal T wave in lead II Normal sinus rhythm	Other localization
			V1 (WEEK 0)	26NOV2009	Infarction, age undetermined in Low voltage of QRS complex in Normal T wave in lead II Normal sinus rhythm	Other localization Limb leads
			V3 (WEEK 12)	18FEB2010	Infarction, age undetermined in Low voltage of QRS complex in Normal T wave in lead II Right atrial abnormality Wandering atrial pacemaker	Other localization Limb leads
			V4 (WEEK 24)	06MAY2010	Complete RBBB Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	011	1	V4 (WEEK 24)	06MAY2010	Right atrial abnormality Right axis deviation	Limb leads
			V5 (WEEK 36)	05AUG2010	Atrial flutter Complete RBBB Isolated atrial premature complex(es) Low voltage of QRS complex in Right axis deviation T wave morphology in lead II: low T wave morphology in lead II: notched	
			V6 (WEEK 52)	26NOV2010	Atrial flutter Complete RBBB Low voltage of QRS complex in Right axis deviation T wave morphology in lead II: low T wave morphology in lead II: notched	
	013	4	SCREENING	17AUG2009	Normal T wave in lead II RSR pattern in lead V1 Sinus bradycardia	
			V1 (WEEK 0)	16SEP2009	Normal T wave in lead II Normal sinus rhythm RSR pattern in lead V1	
			V3 (WEEK 12)	09DEC2009	Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	013	4	V3 (WEEK 12)	09DEC2009	Normal sinus rhythm RSR pattern in lead V1	
			V4 (WEEK 24)	04MAR2010	Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	20MAY2010	Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	16SEP2010	Right atrial abnormality Normal T wave in lead II Normal sinus rhythm RSR pattern in lead V1	
	016	4	SCREENING	01FEB2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	01MAR2010	Normal T wave in lead II Sinus bradycardia T-U waves fusion in	Anterior leads / Inferior leads
			V3 (WEEK 12)	19MAY2010	Normal T wave in lead II Normal sinus rhythm T-U waves fusion in	Anterior leads / Inferior leads
			V4 (WEEK 24)	09AUG2010	Isolated ventricular premature complex(es), monomorphic	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	016	4	V4 (WEEK 24)	09AUG2010	Normal T wave in lead II Sinus bradycardia T-U waves fusion in	Anterior leads / Inferior leads
			V5 (WEEK 36)	08NOV2010	Normal T wave in lead II Normal sinus rhythm T-U waves fusion in	Anterior leads / Inferior leads
			V6 (WEEK 52)	28FEB2011	Normal T wave in lead II Normal sinus rhythm T-U waves fusion in	Anterior leads / Inferior leads
	018	5	SCREENING	03NOV2009	Sinus bradycardia T wave morphology in lead II: low	
			V1 (WEEK 0)	23NOV2009	Isolated atrial premature complex(es) Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	16FEB2010	Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	11MAY2010	Normal T wave in lead II Sinus bradycardia	
			V5 (WEEK 36)	27JUL2010	Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	018	5	V5 (WEEK 36)	27JUL2010	Sinus bradycardia	
			V6 (WEEK 52)	23NOV2010	Normal T wave in lead II Sinus bradycardia	
	020	5	SCREENING	27JAN2010	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)		T-U waves fusion in	Other localization
				22FEB2010	Normal T wave in lead II Sinus bradycardia T-U waves fusion in	Other localization
	024	4	SCREENING	16JUL2010	Complete RBBB Normal T wave in lead II Sinus bradycardia	
				16AUG2010	Complete RBBB Isolated atrial premature complex(es) Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	10NOV2010	Complete RBBB Indeterminate axis Normal T wave in lead II	
					Normal sinus rhythm	
			V4 (WEEK 24)	02FEB2011	Complete RBBB	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	024	4	V4 (WEEK 24)	02FEB2011	Indeterminate axis Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	18APR2011	Complete RBBB Indeterminate axis Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	08AUG2011	Atrial ectopic pacemaker Complete RBBB Indeterminate axis Isolated atrial premature complex(es) Isolated ventricular premature complex(es), monomorphic Normal T wave in lead II	
	028	20	SCREENING	18NOV2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	26NOV2010	Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	22FEB2011	Isolated ventricular premature complex(es), monomorphic Normal T wave in lead II Normal sinus rhythm	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	028	20	V4 (WEEK 24)	24AUG2011	Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	25AUG2011	Normal T wave in lead II Wandering atrial pacemaker	
			V6 (WEEK 52)	24NOV2011	Normal T wave in lead II Wandering atrial pacemaker	
	029	8	SCREENING	26JAN2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	29JAN2010	Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	20APR2010	Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	05JUL2010	Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	30SEP2010	Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	01FEB2011	Normal T wave in lead II Normal sinus rhythm	
	031	8	SCREENING	06MAY2010	Misplaced precordial electrode(s) Normal T wave in lead II	
					Poor R wave progression in precordial leads	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	031	8	SCREENING	06MAY2010	Sinus bradycardia	
			V1 (WEEK 0)	20MAY2010	Misplaced precordial electrode(s)	
					Normal T wave in lead II	
					Normal sinus rhythm	
					Poor R wave progression in precordial leads	
			V3 (WEEK 12)	17AUG2010	Misplaced precordial electrode(s)	
					Normal T wave in lead II	
					Normal sinus rhythm	
					Poor R wave progression in precordial leads	
			V4 (WEEK 24)	09NOV2010	Misplaced precordial electrode(s)	
	034	9			Normal T wave in lead II	
					Normal sinus rhythm	
					Poor R wave progression in precordial leads	
			V5 (WEEK 36)	25JAN2011	Misplaced precordial electrode(s)	
					Normal T wave in lead II	
					Normal sinus rhythm	
					Poor R wave progression in precordial leads	
			V6 (WEEK 52)	17MAY2011	Misplaced precordial electrode(s)	
					Normal T wave in lead II	
					Normal sinus rhythm	
					Poor R wave progression in precordial leads	
			SCREENING	24FEB2010	Junctional escape complex(es)	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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13FEB2013

Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	034	9	SCREENING	24FEB2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	18MAR2010	Junctional escape complex(es) Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	08SEP2010	Junctional escape complex(es) Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	30NOV2010	Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	15MAR2011	Junctional escape complex(es) Normal T wave in lead II Normal sinus rhythm	
	041	12	SCREENING	23SEP2009	Non specific P wave abnormality Sinus bradycardia T wave morphology in lead II: flat	
			V1 (WEEK 0)	09OCT2009	Infarction, age undetermined in Normal T wave in lead II Normal sinus rhythm RSR pattern in lead V1	Other localization
			V3 (WEEK 12)	05JAN2010	Normal T wave in lead II Sinus arrhythmia	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	041	12	V4 (WEEK 24)	24MAR2010	Couplet atrial premature complex(es) Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	16JUN2010	Atrial ectopic pacemaker Normal T wave in lead II Right atrial abnormality	
			V6 (WEEK 52)	06OCT2010	Isolated atrial premature complex(es) Misplaced precordial electrode(s) Non specific P wave abnormality Normal T wave in lead II Prominent U wave in Sinus bradycardia T-U waves fusion in	Antero-septal leads Antero-septal leads
	044	12	SCREENING	04NOV2009	Complete LBBB First degree AV block	
			V1 (WEEK 0)	02DEC2009	Abnormal ST pattern in Complete LBBB First degree AV block Non specific P wave abnormality Normal sinus rhythm T wave morphology in lead II: diphasic (negative-positive)	Septal leads

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	044	12	V3 (WEEK 12)	24FEB2010	Abnormal ST pattern in Complete LBBB First degree AV block Isolated ventricular premature complex(es), monomorphic Non specific P wave abnormality Normal sinus rhythm Poor R wave progression in precordial leads T wave morphology in lead II: diphasic (negative-positive)	Antero-septal leads
			V4 (WEEK 24)	26MAY2010	Abnormal ST pattern in Complete LBBB First degree AV block Non specific P wave abnormality Normal sinus rhythm Poor R wave progression in precordial leads T wave morphology in lead II: diphasic (negative-positive)	Septal leads
			V5 (WEEK 36)	18AUG2010	Abnormal ST pattern in Complete LBBB Isolated atrial premature complex(es) Isolated ventricular premature complex(es), monomorphic	Septal leads

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	044	12	V5 (WEEK 36)	18AUG2010	Normal sinus rhythm Poor R wave progression in precordial leads T wave morphology in lead II: diphasic (negative-positive)	Septal leads
			V6 (WEEK 52)	01DEC2010	Abnormal ST pattern in Complete LBBB First degree AV block Non specific P wave abnormality Normal sinus rhythm Poor R wave progression in precordial leads T wave morphology in lead II: diphasic (negative-positive)	
	045	11	SCREENING	07DEC2009	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	21DEC2009	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	15MAR2010	Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	07JUN2010	Normal T wave in lead II RSR pattern in lead V1 Sinus bradycardia	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	045	11	V5 (WEEK 36)	06SEP2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Normal sinus rhythm	
			V6 (WEEK 52)	15DEC2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	
	047	11	SCREENING	12JUL2010	Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	02AUG2010	Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	20OCT2010	Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	10JAN2011	Normal T wave in lead II Sinus bradycardia	
			V5 (WEEK 36)	12APR2011	Intraventricular conduction disturbance, nonspecific type Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	047	11	V6 (WEEK 52)	27JUL2011	Intraventricular conduction disturbance, nonspecific type Misplaced precordial electrode(s) Normal T wave in lead II Sinus bradycardia	
	049	21	SCREENING	06SEP2010	Atrial ectopic pacemaker Normal T wave in lead II	
			V1 (WEEK 0)	27OCT2010	Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	18JAN2011	Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	12APR2011	Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	05JUL2011	Normal T wave in lead II Normal sinus rhythm	
	051	21	SCREENING	06SEP2010	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads RSR pattern in lead V1	
			V1 (WEEK 0)	28OCT2010	Atrial ectopic pacemaker	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	051	21	V1 (WEEK 0)	28OCT2010	Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads RSR pattern in lead V1	
			V4 (WEEK 24)	12APR2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads RSR pattern in lead V1	
			V5 (WEEK 36)	05JUL2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads RSR pattern in lead V1	
			V6 (WEEK 52)	25OCT2011	Normal T wave in lead II Normal sinus rhythm RSR pattern in lead V1	
	056	5	SCREENING	31MAR2010	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	21APR2010	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	13JUL2010	Normal T wave in lead II	

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	056	5	V3 (WEEK 12)	13JUL2010	Sinus bradycardia	
			V4 (WEEK 24)	05OCT2010	Normal T wave in lead II	
			V5 (WEEK 36)	04JAN2011	Sinus bradycardia	
		6			Left axis deviation	
					Misplaced precordial electrode(s)	
					Non specific ST or T wave abnormalities	
	058				Normal T wave in lead II	
	1	SCREENING	06DEC2010	Poor R wave progression in precordial leads		
				Wandering atrial pacemaker		
				Left axis deviation		
	056	5	V3 (WEEK 12)	13JUL2010	Sinus bradycardia	
			V4 (WEEK 24)	05OCT2010	Normal T wave in lead II	
			V5 (WEEK 36)	04JAN2011	Sinus bradycardia	
		6			Left axis deviation	
					Misplaced precordial electrode(s)	
					Non specific ST or T wave abnormalities	
	058				Normal T wave in lead II	
	1	SCREENING	06DEC2010	Poor R wave progression in precordial leads		
				Wandering atrial pacemaker		
				Left axis deviation		
	056	5	V3 (WEEK 12)	13JUL2010	Sinus bradycardia	
			V4 (WEEK 24)	05OCT2010	Normal T wave in lead II	
			V5 (WEEK 36)	04JAN2011	Sinus bradycardia	
		6			Left axis deviation	
					Misplaced precordial electrode(s)	
					Non specific ST or T wave abnormalities	
	058				Normal T wave in lead II	
	1	SCREENING	06DEC2010	Poor R wave progression in precordial leads		
				Wandering atrial pacemaker		
				Left axis deviation		
	056	5	V3 (WEEK 12)	13JUL2010	Sinus bradycardia	
			V4 (WEEK 24)	05OCT2010	Normal T wave in lead II	
			V5 (WEEK 36)	04JAN2011	Sinus bradycardia	
		6			Left axis deviation	
					Misplaced precordial electrode(s)	
					Non specific ST or T wave abnormalities	
	058				Normal T wave in lead II	
	1	SCREENING	06DEC2010	Poor R wave progression in precordial leads		
				Wandering atrial pacemaker		
				Left axis deviation		
	056	5	V3 (WEEK 12)	13JUL2010	Sinus bradycardia	
			V4 (WEEK 24)	05OCT2010	Normal T wave in lead II	
			V5 (WEEK 36)	04JAN2011	Sinus bradycardia	
		6			Left axis deviation	
					Misplaced precordial electrode(s)	
					Non specific ST or T wave abnormalities	
	058				Normal T wave in lead II	
	1	SCREENING	06DEC2010	Poor R wave progression in precordial leads		
				Wandering atrial pacemaker		
				Left axis deviation		
	056	5	V3 (WEEK 12)	13JUL2010	Sinus bradycardia	
			V4 (WEEK 24)	05OCT2010	Normal T wave in lead II	
			V5 (WEEK 36)	04JAN2011	Sinus bradycardia	
		6			Left axis deviation	
					Misplaced precordial electrode(s)	
					Non specific ST or T wave abnormalities	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	058	1	V6 (WEEK 52)	06DEC2011	Normal T wave in lead II Wandering atrial pacemaker	
	059	1	SCREENING	27DEC2010	Abnormal ST pattern in Normal sinus rhythm Short PR interval T wave morphology in lead II: diphasic (negative-positive) T-U waves fusion in	Inferior leads / Antero-lateral leads
			V1 (WEEK 0)	29DEC2010	Abnormal ST pattern in Normal sinus rhythm Short PR interval T wave morphology in lead II: flat T-U waves fusion in	Anterior leads / Other localization Other localization
			V3 (WEEK 12)	31MAR2011	Abnormal ST pattern in Normal sinus rhythm Short PR interval T wave morphology in lead II: flat	Other localization
			V5 (WEEK 36)	08SEP2011	Abnormal ST pattern in Normal sinus rhythm Short PR interval	Other localization

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification	
Placebo	059	1	V5 (WEEK 36)	08SEP2011	T wave morphology in lead II: flat T-U waves fusion in	Other localization	
			V6 (WEEK 52)	08DEC2011	Abnormal ST pattern in Normal sinus rhythm Short PR interval T wave morphology in lead II: flat T-U waves fusion in	Other localization Other localization	
		065	16	SCREENING	10AUG2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	Other localization
				V1 (WEEK 0)	30AUG2010	Atrial ectopic pacemaker Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II	
	V3 (WEEK 12)		22NOV2010	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia			
	V4 (WEEK 24)		17JAN2011	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II			

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	065	16	V4 (WEEK 24)	17JAN2011	Sinus bradycardia	
	068	16	SCREENING	26OCT2010	Atrial ectopic pacemaker Normal T wave in lead II	
			V1 (WEEK 0)	22NOV2010	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	10FEB2011	Misplaced precordial electrode(s) Normal T wave in lead II Wandering atrial pacemaker	
			V4 (WEEK 24)	03MAY2011	Misplaced precordial electrode(s) Normal T wave in lead II Wandering atrial pacemaker	
			V5 (WEEK 36)	10AUG2011	Atrial ectopic pacemaker Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads	
			V6 (WEEK 52)	28NOV2011	Atrial ectopic pacemaker Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads	
	069	23	SCREENING	24NOV2010	Non specific ST or T wave abnormalities Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	069	23	SCREENING	24NOV2010	T wave morphology in lead II: low	
			V3 (WEEK 12)	09MAR2011	Non specific ST or T wave abnormalities Normal sinus rhythm	
			V4 (WEEK 24)	19MAY2011	T wave morphology in lead II: low Non specific ST or T wave abnormalities Normal sinus rhythm	
			V5 (WEEK 36)	24AUG2011	T wave morphology in lead II: flat Atrial ectopic pacemaker	
	072	18	V6 (WEEK 52)	14DEC2011	Non specific ST or T wave abnormalities T wave morphology in lead II: flat Normal sinus rhythm T wave morphology in lead II: flat	
			SCREENING	01DEC2010	Normal T wave in lead II Wandering atrial pacemaker	
			V1 (WEEK 0)	21DEC2010	Normal T wave in lead II Wandering atrial pacemaker	
			V3 (WEEK 12)	19MAR2011	Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads Wandering atrial pacemaker	
			V4 (WEEK 24)	07JUN2011	Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	072	18	V4 (WEEK 24)	07JUN2011	Sinus bradycardia	
			V5 (WEEK 36)	08SEP2011	Atrial ectopic pacemaker Normal T wave in lead II	
			V6 (WEEK 52)	15DEC2011	Normal T wave in lead II Sinus bradycardia	
	079	13	UNSCHEDULED	19JUL2011	Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	06AUG2010	Normal T wave in lead II Sinus bradycardia	
			V3 (WEEK 12)	09NOV2010	Normal T wave in lead II Sinus bradycardia	
			V4 (WEEK 24)	27JAN2011	Normal T wave in lead II Wandering atrial pacemaker	
			V5 (WEEK 36)	11APR2011	Normal T wave in lead II Sinus bradycardia	
			V6 (WEEK 52)	21JUN2011	Normal T wave in lead II Normal sinus rhythm	
	082	17	SCREENING	06OCT2010	Incomplete RBBB Normal T wave in lead II Sinus bradycardia	
			V1 (WEEK 0)	14OCT2010	Incomplete RBBB	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	082	17	V1 (WEEK 0)	14OCT2010	Normal T wave in lead II Normal sinus rhythm	
			V3 (WEEK 12)	05JAN2011	Incomplete RBBB Normal T wave in lead II Normal sinus rhythm	
			V4 (WEEK 24)	06APR2011	Incomplete RBBB Normal T wave in lead II Normal sinus rhythm	
			V5 (WEEK 36)	22JUN2011	Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Sinus bradycardia	
			V6 (WEEK 52)	12OCT2011	Borderline first degree AV block Intraventricular conduction disturbance, nonspecific type Normal T wave in lead II Normal sinus rhythm	
	084	17	SCREENING	08NOV2010	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm	
			V1 (WEEK 0)	17NOV2010	Poor R wave progression in precordial leads Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	084	17	V1 (WEEK 0)	17NOV2010	Normal sinus rhythm	
			V3 (WEEK 12)	08FEB2011	Normal T wave in lead II	
					Normal sinus rhythm	
			V4 (WEEK 24)	10MAY2011	Non specific ST or T wave abnormalities	
					Normal sinus rhythm	
					T wave morphology in lead II: low	
	086	21	V5 (WEEK 36)	02AUG2011	Non specific ST or T wave abnormalities	
					Normal sinus rhythm	
					T wave morphology in lead II: low	
			V6 (WEEK 52)	22NOV2011	Isolated ventricular premature complex(es), monomorphic	
					Non specific ST or T wave abnormalities	
					Sinus bradycardia	
					T wave morphology in lead II: low	
					Isolated ventricular premature complex(es), monomorphic	
					Misplaced precordial electrode(s)	
					Normal T wave in lead II	
					Poor R wave progression in precordial leads	
					Wandering atrial pacemaker	
			V1 (WEEK 0)	28OCT2010	Misplaced precordial electrode(s)	
					Normal T wave in lead II	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	086	21	V1 (WEEK 0)	28OCT2010	Poor R wave progression in precordial leads Sinus bradycardia	
			V3 (WEEK 12)	18JAN2011	Junctional escape complex(es) Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads Wandering atrial pacemaker	
			V4 (WEEK 24)	12APR2011	Isolated atrial premature complex(es) Misplaced precordial electrode(s) Normal T wave in lead II Poor R wave progression in precordial leads Sinus bradycardia	
			V5 (WEEK 36)	05JUL2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	
			V6 (WEEK 52)	25OCT2011	Misplaced precordial electrode(s) Normal T wave in lead II Normal sinus rhythm Poor R wave progression in precordial leads	
	088	16	SCREENING	30NOV2010	Normal T wave in lead II Normal sinus rhythm	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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Interpretation

Treat- ment	Random No.	Site ID	Visit	Date	Interpretation	Specification
Placebo	088	16	V1 (WEEK 0)	09DEC2010	Normal T wave in lead II Normal sinus rhythm Short PR interval	
			V3 (WEEK 12)	01MAR2011	Atrial ectopic pacemaker Normal T wave in lead II Short PR interval	
			V4 (WEEK 24)	19MAY2011	Atrial ectopic pacemaker Normal T wave in lead II Short PR interval	
			V5 (WEEK 36)	29AUG2011	Atrial ectopic pacemaker Normal T wave in lead II Short PR interval	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	002	1	SCREENING	-7	16APR2009	9:47	YES	NO	
			V1 (WEEK 0)	1	23APR2009	8:35	YES	NO	
			V3 (WEEK 12)	85	16JUL2009	10:19	YES	NO	
			V4 (WEEK 24)	169	08OCT2009	10:25	YES	NO	
			V5 (WEEK 36)	258	05JAN2010	9:13	YES	NO	
			V6 (WEEK 52)	365	22APR2010	9:41	YES	NO	
	004	1	SCREENING	-29	17JUN2009	11:29	YES	NO	
			V1 (WEEK 0)	1	16JUL2009	13:52	YES	NO	
			V3 (WEEK 12)	92	15OCT2009	15:05	YES	NO	
	006	2	SCREENING	-32	25JAN2010	10:32	YES	NO	
			V1 (WEEK 0)	1	26FEB2010	10:31	YES	NO	
			V3 (WEEK 12)	85	21MAY2010	10:11	YES	NO	
			V4 (WEEK 24)	169	13AUG2010	9:00	YES	NO	
			V5 (WEEK 36)	252	04NOV2010	9:00	YES	NO	
			V6 (WEEK 52)	364	24FEB2011	11:16	YES	NO	
	010	1	SCREENING	-26	26JUN2009	9:22	YES	NO	
			V1 (WEEK 0)	1	21JUL2009	14:58	YES	NO	
			V3 (WEEK 12)	85	13OCT2009	10:30	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	012	1	SCREENING	-32	17JUN2010	11:15	YES	YES	RIGHT BUNDLE BRANCH BLOCK, LEFT ANTERIOR HEMIBLOCK, SIGNS OF OLD INFARCT
			V1 (WEEK 0)	1	19JUL2010	9:34	YES	YES	RIGHT BUNDLE BRANCH BLOCK, LEFT ARTERIAL HEMIBLOCK, SIGNS OF OLD INFARCT
			V3 (WEEK 12)	88	14OCT2010	9:30	YES	YES	RIGHT BUNDLE BRANCHBLOCK, LEFT ANTERIOR HEMIBLOCK, SIGNS OF OLD INFARCT, BRADYCARDIA
			V4 (WEEK 24)	176	10JAN2011	10:39	YES	YES	RIGHT BUNDLE BRANCH BLOCK, LEFT ANTERIOR HEMIBLOCK, SIGNS OF OLD INFARCT, BRADYCARDIA
			V5 (WEEK 36)	257	01APR2011	10:31	YES	YES	RIGHT BUNDLE BRANCH BLOCK, LEFT AUTIOR HEMIBLOCK, SIGNS OF OLD INFARCT, BRADYKARDIA.
			V6 (WEEK 52)	361	14JUL2011				
	014	4	SCREENING	-26	07OCT2009	11:19	YES	NO	
			V1 (WEEK 0)	1	02NOV2009	11:49	YES	NO	AS DESCRIBED IN PREVIOUS ECG: T-NEGATIVATION IN III AND AVF, FLATTENED T IN V4 - V6
			V3 (WEEK 12)	85	25JAN2010	11:35	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	014	4	V4 (WEEK 24)	172	22APR2010	12:43	YES	NO	
			V5 (WEEK 36)	256	15JUL2010	12:05	YES	NO	
			V6 (WEEK 52)	361	28OCT2010	14:29	YES	NO	
	015	4	SCREENING	-32	21JAN2010	12:46	YES	NO	
			V1 (WEEK 0)	1	22FEB2010	12:03	YES	NO	
			V3 (WEEK 12)	85	17MAY2010	11:33	YES	NO	
			V4 (WEEK 24)	162	02AUG2010	11:36	YES	NO	
			V5 (WEEK 36)	248	27OCT2010	12:06	YES	NO	
			V6 (WEEK 52)	365	21FEB2011	11:25	YES	NO	
	017	5	SCREENING	-22	14JUL2009	10:24	YES	NO	
			UNSCHEDULED	9		10:39	YES	NO	
			V1 (WEEK 0)	1	05AUG2009	10:31	YES	NO	
			V3 (WEEK 12)	85	28OCT2009	9:00	YES	NO	
			V4 (WEEK 24)	169	20JAN2010	9:04	YES	NO	
			V5 (WEEK 36)	252	13APR2010	10:54	YES	NO	
	019	5	V6 (WEEK 52)	364	03AUG2010	9:17	YES	NO	
			SCREENING	-21	18NOV2009	14:26	YES	NO	
			V1 (WEEK 0)	1	09DEC2009	9:16	YES	NO	
			V3 (WEEK 12)	85	03MAR2010	9:02	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	019	5	V4 (WEEK 24)	168	25MAY2010	9:05	YES	NO	
			V5 (WEEK 36)	259	24AUG2010	11:59	YES	NO	
			V6 (WEEK 52)	364	07DEC2010	9:16	YES	NO	
	023	4	SCREENING	-19	01JUL2010	13:05	YES	NO	
			V1 (WEEK 0)	1	20JUL2010	12:30	YES	NO	
			V3 (WEEK 12)	86	13OCT2010	12:30	YES	NO	
			V4 (WEEK 24)	177	12JAN2011	13:57	YES	NO	
			V5 (WEEK 36)	245	21MAR2011	12:22	YES	YES	SLIGHT INCREASE OF QTC (445MS) COMPARED TO ECG OF 12.01.11 (437)
			V6 (WEEK 52)	364	18JUL2011	14:10	YES	YES	SLIGHT INCREASE OF QTC TO 453 MS (PREVIOUS VALUE 445 MS AT VISIT 5)
	027	20	SCREENING	-21	30SEP2010	9:39	YES	NO	
			V1 (WEEK 0)	1	21OCT2010	11:55	YES	NO	
			V3 (WEEK 12)	92	20JAN2011	11:05	YES	NO	
			V4 (WEEK 24)	174	12APR2011	14:33	YES	NO	
			V5 (WEEK 36)	259	06JUL2011	10:07	YES	NO	
			V6 (WEEK 52)	370	25OCT2011	9:34	YES	NO	
	030	8	SCREENING	-7	18MAR2010	13:16	YES	NO	
			V1 (WEEK 0)	1	25MAR2010	12:25	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	030	8	V3 (WEEK 12)	85	17JUN2010	13:06	YES	NO	
			V4 (WEEK 24)	163	03SEP2010	13:01	YES	NO	
			V5 (WEEK 36)	253	02DEC2010	12:56	YES	NO	
			V6 (WEEK 52)	355	14MAR2011	12:50	YES	NO	
	032	8	SCREENING	-10	08NOV2010	11:23	YES	NO	
			V1 (WEEK 0)	1	18NOV2010	12:39	YES	NO	
			V3 (WEEK 12)	82	07FEB2011	12:00	YES	NO	
	033	9	SCREENING	-7	28OCT2009	10:50	YES	NO	
			V1 (WEEK 0)	1	04NOV2009	10:50	YES	NO	
			V3 (WEEK 12)	78	20JAN2010	10:00	YES	NO	
			V4 (WEEK 24)	169	21APR2010	10:17	YES	NO	
			V6 (WEEK 52)	372	10NOV2010	9:43	YES	NO	
	042	12	SCREENING	-29	16DEC2009	9:15	YES	NO	
			V1 (WEEK 0)	1	14JAN2010	9:00	YES	NO	
			V3 (WEEK 12)	126	19MAY2010	8:50	YES	NO	
			V4 (WEEK 24)	168	30JUN2010	9:30	YES	NO	
			V5 (WEEK 36)	252	22SEP2010	9:20	YES	NO	
			V6 (WEEK 52)	364	12JAN2011	10:05	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	043	12	SCREENING	-28	21OCT2009	10:00	YES	NO	
			V1 (WEEK 0)	1	18NOV2009	9:30	YES	NO	
			V3 (WEEK 12)	85	10FEB2010	9:20	YES	NO	
			V4 (WEEK 24)	176	12MAY2010	8:30	YES	NO	
	046	11	SCREENING	-28	14DEC2009	10:00	YES	YES	QTC WITH 454 MS VENTRICULAR AND SUPRAVENTRICULAR EXTRA SYSTOLE
			V1 (WEEK 0)	1	11JAN2010	10:42	YES	YES	
			V3 (WEEK 12)	87	07APR2010	11:15	YES	NO	
			V4 (WEEK 24)	178	07JUL2010	12:15	YES	NO	
			V5 (WEEK 36)	255	22SEP2010	13:07	YES	NO	
			V6 (WEEK 52)	367	12JAN2011	12:36	YES	NO	
	048	11	SCREENING	-5	17NOV2010	12:15	YES	NO	
			V1 (WEEK 0)	1	22NOV2010	12:15	YES	NO	
			V3 (WEEK 12)	86	15FEB2011	11:20	YES	NO	
			V4 (WEEK 24)	176	16MAY2011	9:42	YES	NO	
			V5 (WEEK 36)	247	26JUL2011	10:37	YES	NO	
			V6 (WEEK 52)	360	16NOV2011	12:34	YES	NO	
	050	21	SCREENING	-51	06SEP2010	16:33	YES	YES	NON CORONARY NEGATIVE T IN LEAD 3
			V1 (WEEK 0)	1	27OCT2010	12:00	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	050	21	V3 (WEEK 12)	83	17JAN2011	13:39	YES	NO	PERIPHERAL LOW VOLTAGE
			V4 (WEEK 24)	167	11APR2011	11:53	YES	NO	
			V5 (WEEK 36)	251	04JUL2011	11:56	YES	YES	
			V6 (WEEK 52)	363	24OCT2011	9:35	YES	NO	
	052	21	SCREENING	-52	06SEP2010	14:42	YES	NO	
			V1 (WEEK 0)	1	28OCT2010	9:01	YES	NO	
			V3 (WEEK 12)	82	17JAN2011	12:29	YES	NO	
			V4 (WEEK 24)	166	11APR2011	11:19	YES	NO	
			V5 (WEEK 36)	250	04JUL2011	9:29	YES	NO	
			V6 (WEEK 52)	362	24OCT2011	12:44	YES	NO	
	055	5	SCREENING	-21	08MAR2010	11:39	YES	NO	
			V1 (WEEK 0)	1	29MAR2010	9:33	YES	NO	
			V6 (WEEK 52)	30	27APR2010	9:25	YES	NO	
	057	1	SCREENING	-21	29JUL2010	10:09	YES	NO	
			V1 (WEEK 0)	1	19AUG2010	11:01	YES	NO	
			V3 (WEEK 12)	82	08NOV2010	10:13	YES	NO	
			V4 (WEEK 24)	170	04FEB2011	9:25	YES	NO	
	066	16	SCREENING	-31	09AUG2010	10:52	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	066	16	V1 (WEEK 0)	1	09SEP2010	9:20	YES	NO	
			V3 (WEEK 12)	83	30NOV2010	9:22	YES	NO	
	067	16	SCREENING	-16	02NOV2010	9:50	YES	NO	
			V1 (WEEK 0)	1	18NOV2010	8:57	YES	NO	
			V6 (WEEK 52)	69	25JAN2011	10:56	YES	NO	
	071	18	SCREENING	-20	20OCT2010	9:56	YES	NO	
			V1 (WEEK 0)	1	09NOV2010	11:20	YES	NO	
			V3 (WEEK 12)	87	03FEB2011	9:49	YES	NO	
			V4 (WEEK 24)	177	04MAY2011	9:49	YES	NO	
			V5 (WEEK 36)	253	19JUL2011	10:01	YES	NO	
			V6 (WEEK 52)	374	17NOV2011	10:45	YES	NO	
	080	13	SCREENING	-10	08NOV2010	10:31	YES	NO	
			UNSCHEDULED	42		15:26	YES	NO	
			V1 (WEEK 0)	1	18NOV2010	12:08	YES	NO	
			V3 (WEEK 12)	84	09FEB2011	13:08	YES	NO	
			V6 (WEEK 52)	196	01JUN2011	12:46	YES	NO	
	081	17	SCREENING	-10	04OCT2010	11:38	YES	NO	
			V1 (WEEK 0)	1	14OCT2010	9:28	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	11:45	YES	NO	
			V4 (WEEK 24)	175	06APR2011	11:30	YES	NO	
			V5 (WEEK 36)	250	20JUN2011	11:09	YES	NO	
			V6 (WEEK 52)	376	24OCT2011	10:58	YES	NO	
	083	17	SCREENING	-15	26OCT2010	13:02	YES	NO	
			V1 (WEEK 0)	1	10NOV2010	11:46	YES	NO	
			V4 (WEEK 24)	168	26APR2011	10:00	YES	NO	
			V6 (WEEK 52)	365	09NOV2011	9:59	YES	NO	
	087	16	SCREENING	-20	09NOV2010	9:18	YES	NO	
			V1 (WEEK 0)	1	29NOV2010	10:07	YES	NO	
			V3 (WEEK 12)	81	17FEB2011	9:59	YES	NO	
			V4 (WEEK 24)	169	16MAY2011	10:55	YES	NO	
			V5 (WEEK 36)	255	10AUG2011	10:29	YES	NO	
			V6 (WEEK 52)	365	28NOV2011	10:04	YES	NO	
	089	5	SCREENING	-28	19OCT2010	12:11	YES	NO	
			V1 (WEEK 0)	1	16NOV2010	9:06	YES	NO	
			V3 (WEEK 12)	84	07FEB2011	11:30	YES	YES	AV-BLOCK FIRST DEGREE
			V4 (WEEK 24)	168	02MAY2011	10:31	YES	NO	
			V5 (WEEK 36)	252	25JUL2011	11:57	YES	NO	

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
ACI-91	089	5	V6 (WEEK 52)	364	14NOV2011	12:36	YES	NO	
		17	SCREENING	-3	29NOV2010	13:17	YES	NO	
	093		V1 (WEEK 0)	1	02DEC2010	12:47	YES	NO	
			V3 (WEEK 12)	86	25FEB2011	13:12	YES	NO	
			V4 (WEEK 24)	173	23MAY2011	12:00	YES	NO	
			V6 (WEEK 52)	370	06DEC2011	11:34	YES	NO	
	097	12	SCREENING	-21	27OCT2010	9:40	YES	NO	
			V1 (WEEK 0)	1	17NOV2010	8:45	YES	NO	
			V3 (WEEK 12)	85	09FEB2011	8:40	YES	NO	
Placebo	001	1	SCREENING	-7	02APR2009	10:30	YES	YES	LEFT BUNDLE BRANCH BLOCK
			V1 (WEEK 0)	1	09APR2009	10:19	YES	YES	LEFT BUNDLE BRANCH BLOCK
			V3 (WEEK 12)	90	07JUL2009	9:12	YES	YES	LEFT BUNDLE BRANCH BLOCK
			V4 (WEEK 24)	162	17SEP2009	10:50	YES	YES	LEFT ANTERIOR HEMI BUNDLE BRANCH BLOCK
			V5 (WEEK 36)	246	10DEC2009	9:04	YES	YES	LEFT ANTERIOR HEMI BUNDLE BRANCH BLOCK
			V6 (WEEK 52)	365	08APR2010	9:37	YES	YES	LEFT ANTERIOR HEMIBUNDLE BRANCH BLOCK

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	003	1	SCREENING	-21	07MAY2009	10:18	YES	NO	
			V1 (WEEK 0)	1	28MAY2009	11:23	YES	NO	
			V3 (WEEK 12)	90	25AUG2009	10:39	YES	NO	
			V4 (WEEK 24)	169	12NOV2009	10:03	YES	NO	
	005	2	SCREENING	-16	19MAY2009	14:09	YES	NO	
			V1 (WEEK 0)	1	04JUN2009	8:52	YES	NO	
			V3 (WEEK 12)	83	25AUG2009	9:05	YES	NO	
			V4 (WEEK 24)	168	18NOV2009	11:43	YES	NO	
			V5 (WEEK 36)	258	16FEB2010	10:27	YES	NO	
			V6 (WEEK 52)	364	02JUN2010	9:15	YES	NO	
	009	1	SCREENING	-33	06AUG2009	12:50	YES	NO	
			V1 (WEEK 0)	1	08SEP2009	9:25	YES	NO	
			V3 (WEEK 12)	94	10DEC2009	10:07	YES	NO	
			V4 (WEEK 24)	178	04MAR2010	12:54	YES	NO	
			V5 (WEEK 36)	246	11MAY2010	9:08	YES	NO	
			V6 (WEEK 52)	361	03SEP2010	10:45	YES	NO	
	011	1	SCREENING	-21	05NOV2009	13:24	YES	NO	
			V1 (WEEK 0)	1	26NOV2009	10:39	YES	NO	
			V3 (WEEK 12)	85	18FEB2010	10:38	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	011	1	V4 (WEEK 24)	162	06MAY2010	12:47	YES	YES	RIGHT BUNDLE BRANCH BLOCK
			V5 (WEEK 36)	253	05AUG2010	11:23	YES	YES	RIGHT BUNDLE BRANCH BLOCK
			V6 (WEEK 52)	366	26NOV2010	10:02	YES	YES	RIGHT BUNDLE BRANCH BLOCK
	013	4	SCREENING	-30	17AUG2009	12:23	YES	YES	T-NEGATIVATION ON V2, BORDERLINE SOKOLOW INDEX
			V1 (WEEK 0)	1	16SEP2009	9:29	YES	YES	T-NEGATIVATION IN V1 - V3, SOKOLW INDEX IS NOT NEGATIV
			V3 (WEEK 12)	85	09DEC2009	11:53	YES	NO	AS PREVIOUSLY DESCRIBED: T-NEGATIVATION IN V1 - V3, SOKOLOW INDEX POSITIVE (SEE ECG OF 18/09/09)
			V4 (WEEK 24)	170	04MAR2010	13:00	YES	NO	
			V5 (WEEK 36)	247	20MAY2010	12:29	YES	NO	
			V6 (WEEK 52)	366	16SEP2010	14:23	YES	NO	
	016	4	SCREENING	-28	01FEB2010	12:07	YES	NO	
			V1 (WEEK 0)	1	01MAR2010	12:26	YES	NO	
			V3 (WEEK 12)	80	19MAY2010	11:12	YES	NO	
			V4 (WEEK 24)	162	09AUG2010	12:24	YES	NO	
			V5 (WEEK 36)	253	08NOV2010	11:42	YES	NO	
			V6 (WEEK 52)	365	28FEB2011	14:31	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	018	5	SCREENING	-20	03NOV2009	13:17	YES	NO	
			V1 (WEEK 0)	1	23NOV2009	12:56	YES	NO	
			V3 (WEEK 12)	86	16FEB2010	9:24	YES	NO	
			V4 (WEEK 24)	170	11MAY2010	9:07	YES	NO	
			V5 (WEEK 36)	247	27JUL2010	9:07	YES	NO	
			V6 (WEEK 52)	366	23NOV2010	9:23	YES	NO	
	020	5	SCREENING	-26	27JAN2010	15:50	YES	NO	
			V1 (WEEK 0)	1	22FEB2010	13:39	YES	NO	
	024	4	SCREENING	-31	16JUL2010	12:17	YES	YES	RIGHT BUNDLE BRANCH BLOCK
			V1 (WEEK 0)	1	16AUG2010	12:23	YES	NO	
			V3 (WEEK 12)	87	10NOV2010	10:41	YES	NO	
			V4 (WEEK 24)	171	02FEB2011	12:17	YES	NO	
			V5 (WEEK 36)	246	18APR2011	12:04	YES	NO	
			V6 (WEEK 52)	358	08AUG2011	13:59	YES	YES	VENTRICULAR EXTRASYSTOLES IN ADDITION TO THE KNOWN RIGHT BUNDLE BRANCH BLOCK
	028	20	SCREENING	-8	18NOV2010	10:30	YES	NO	
			V1 (WEEK 0)	1	26NOV2010	10:58	YES	NO	
			V3 (WEEK 12)	89	22FEB2011	10:38	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	028	20	V4 (WEEK 24)	180	24MAY2011	10:30	YES	NO	
			V5 (WEEK 36)	273	25AUG2011	14:26	YES	NO	
			V6 (WEEK 52)	364	24NOV2011	10:54	YES	NO	
	029	8	SCREENING	-3	26JAN2010	12:09	YES	NO	
			V1 (WEEK 0)	1	29JAN2010	12:31	YES	NO	
			V3 (WEEK 12)	82	20APR2010	12:03	YES	NO	
			V4 (WEEK 24)	158	05JUL2010	11:28	YES	NO	
			V5 (WEEK 36)	245	30SEP2010	12:23	YES	NO	
			V6 (WEEK 52)	369	01FEB2011	11:32	YES	NO	
	031	8	SCREENING	-14	06MAY2010	13:54	YES	NO	
			V1 (WEEK 0)	1	20MAY2010	11:52	YES	NO	
			V3 (WEEK 12)	90	17AUG2010	10:25	YES	NO	
			V4 (WEEK 24)	174	09NOV2010	9:09	YES	NO	
			V5 (WEEK 36)	251	25JAN2011	11:48	YES	NO	
			V6 (WEEK 52)	363	17MAY2011	12:57	YES	NO	
	034	9	SCREENING	-22	24FEB2010	9:00	YES	NO	
			V1 (WEEK 0)	1	18MAR2010	8:43	YES	NO	
			V4 (WEEK 24)	175	08SEP2010	8:55	YES	NO	
			V5 (WEEK 36)	258	30NOV2010	9:44	YES	NO	

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	034	9	V6 (WEEK 52)	363	15MAR2011	9:42	YES	NO	
	041	12	SCREENING	-16	23SEP2009	11:27	YES	NO	
			V1 (WEEK 0)	1	09OCT2009	9:26	YES	NO	
			V3 (WEEK 12)	89	05JAN2010	9:30	YES	NO	
			V4 (WEEK 24)	167	24MAR2010	8:58	YES	NO	
			V5 (WEEK 36)	251	16JUN2010	9:00	YES	NO	
			V6 (WEEK 52)	363	06OCT2010	9:10	YES	NO	
	044	12	SCREENING	-28	04NOV2009	9:45	YES	NO	
			V1 (WEEK 0)	1	02DEC2009	9:15	YES	NO	
			V3 (WEEK 12)	85	24FEB2010	9:10	YES	NO	
			V4 (WEEK 24)	176	26MAY2010	9:00	YES	NO	
			V5 (WEEK 36)	260	18AUG2010	9:00	YES	NO	
			V6 (WEEK 52)	365	01DEC2010	8:30	YES	NO	
	045	11	SCREENING	-14	07DEC2009	10:00	YES	NO	
			V1 (WEEK 0)	1	21DEC2009	10:05	YES	NO	
			V3 (WEEK 12)	85	15MAR2010	9:00	YES	NO	
			V4 (WEEK 24)	169	07JUN2010	9:30	YES	NO	
			V5 (WEEK 36)	260	06SEP2010	9:34	YES	NO	
			V6 (WEEK 52)	360	15DEC2010	10:48	YES	NO	

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	047	11	SCREENING	-21	12JUL2010	7:46	YES	NO	
			V1 (WEEK 0)	1	02AUG2010	8:32	YES	NO	
			V3 (WEEK 12)	80	20OCT2010	11:24	YES	NO	
			V4 (WEEK 24)	162	10JAN2011	10:55	YES	NO	
			V5 (WEEK 36)	254	12APR2011	9:43	YES	NO	
			V6 (WEEK 52)	360	27JUL2011	11:36	YES	NO	
	049	21	SCREENING	-51	06SEP2010	12:30	YES	YES	SINUS BRADYCARDIA, AV BLOCK 1
			UNSCHEDULED	302		10:42	YES	NO	
			V1 (WEEK 0)	1	27OCT2010	9:09	YES	NO	
			V3 (WEEK 12)	84	18JAN2011	12:08	YES	NO	
			V4 (WEEK 24)	168	12APR2011	11:08	YES	NO	
			V5 (WEEK 36)	252	05JUL2011	10:05	YES	NO	
	051	21	SCREENING	-52	06SEP2010	14:08	YES	NO	SLOW R WAVE PROGRESSION
			V1 (WEEK 0)	1	28OCT2010	14:44	YES	NO	
			V3 (WEEK 12)	97	01FEB2011	11:35	YES	NO	
			V4 (WEEK 24)	167	12APR2011	13:37	YES	YES	
			V5 (WEEK 36)	251	05JUL2011	13:47	YES	NO	
			V6 (WEEK 52)	363	25OCT2011	9:05	YES	NO	
	056	5	SCREENING	-21	31MAR2010	10:32	YES	NO	

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	056	5	V1 (WEEK 0)	1	21APR2010	9:19	YES	NO	
			V3 (WEEK 12)	84	13JUL2010	10:17	YES	NO	
			V4 (WEEK 24)	168	05OCT2010	9:18	YES	NO	
			V5 (WEEK 36)	259	04JAN2011	9:05	YES	NO	
			V6 (WEEK 52)	364	19APR2011	8:16	YES	NO	
	058	1	SCREENING	-21	06DEC2010	9:48	YES	NO	
			V1 (WEEK 0)	1	27DEC2010	11:10	YES	NO	
			V3 (WEEK 12)	93	29MAR2011	10:30	YES	NO	
			V4 (WEEK 24)	166	10JUN2011	10:28	YES	NO	
			V5 (WEEK 36)	260	12SEP2011	10:08	YES	NO	
			V6 (WEEK 52)	345	06DEC2011	10:36	YES	NO	
	059	1	SCREENING	-2	27DEC2010	13:16	YES	YES	SHORT PQ-TIME, ABNORMAL REPOLARISATION IN V3-V6
			V1 (WEEK 0)	1	29DEC2010	10:27	YES	YES	SHORT PQ-TIME, ABNORMAL REPOLARISATION IN V3-V6
			V3 (WEEK 12)	93	31MAR2011	10:04	YES	YES	SHORT PQ-TIME, ABNORMAL REPOLARISATION IN V4-V6
			V4 (WEEK 24)	161	07JUN2011				
			V5 (WEEK 36)	254	08SEP2011	9:53	YES	YES	PQ-TIME > 0,1 SEC
			V6 (WEEK 52)	345	08DEC2011	10:35	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	065	16	SCREENING	-20	10AUG2010	11:11	YES	NO	
			V1 (WEEK 0)	1	30AUG2010	9:33	YES	NO	
			V3 (WEEK 12)	85	22NOV2010	11:06	YES	NO	
			V4 (WEEK 24)	141	17JAN2011	10:52	YES	NO	
	068	16	SCREENING	-27	26OCT2010	8:59	YES	NO	
			V1 (WEEK 0)	1	22NOV2010	9:58	YES	NO	
			V3 (WEEK 12)	81	10FEB2011	9:32	YES	NO	
			V4 (WEEK 24)	163	03MAY2011	10:20	YES	NO	
			V5 (WEEK 36)	262	10AUG2011	9:21	YES	NO	
			V6 (WEEK 52)	372	28NOV2011	10:23	YES	NO	
	069	23	SCREENING	-13	24NOV2010	9:11	YES	NO	
			V3 (WEEK 12)	93	09MAR2011	11:58	YES	NO	
			V4 (WEEK 24)	164	19MAY2011	9:30	YES	NO	
			V5 (WEEK 36)	261	24AUG2011	11:23	YES	NO	
			V6 (WEEK 52)	373	14DEC2011	8:30	YES	NO	
	072	18	SCREENING	-20	01DEC2010	10:42	YES	NO	
			V1 (WEEK 0)	1	21DEC2010	12:36	YES	NO	
			V3 (WEEK 12)	85	15MAR2011	9:44	YES	NO	
			V4 (WEEK 24)	169	07JUN2011	10:13	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	072	18	V5 (WEEK 36)	262	08SEP2011	10:25	YES	NO	
			V6 (WEEK 52)	360	15DEC2011	9:43	YES	NO	
	079	13	SCREENING	-18	19JUL2010	14:52	YES	NO	
			V1 (WEEK 0)	1	06AUG2010	10:16	YES	NO	
			V3 (WEEK 12)	96	09NOV2010	12:48	YES	NO	
			V4 (WEEK 24)	175	27JAN2011	14:38	YES	NO	
			V5 (WEEK 36)	249	11APR2011	11:34	YES	NO	
			V6 (WEEK 52)	320	21JUN2011	12:03	YES	NO	
	082	17	SCREENING	-8	06OCT2010	10:46	YES	NO	
			V1 (WEEK 0)	1	14OCT2010	10:09	YES	NO	
			V3 (WEEK 12)	84	05JAN2011	11:57	YES	NO	
			V4 (WEEK 24)	175	06APR2011	11:27	YES	NO	
			V5 (WEEK 36)	252	22JUN2011	11:49	YES	NO	
			V6 (WEEK 52)	364	12OCT2011	12:32	YES	NO	
	084	17	SCREENING	-9	08NOV2010	10:19	YES	NO	
			V1 (WEEK 0)	1	17NOV2010	14:08	YES	NO	
			V3 (WEEK 12)	84	08FEB2011	10:49	YES	NO	
			V4 (WEEK 24)	175	10MAY2011	11:03	YES	NO	
			V5 (WEEK 36)	259	02AUG2011	11:51	YES	NO	

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Listing 16.2.9.2.1: Electrocardiogram (ECG) 12-lead

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ECG evaluation by investigator

Treat- ment	Random No.	Site ID	Visit	Actual day	ECG		Result reviewed	Clinic. signif. finding	Specification if clinically significant finding
					Date	Time			
Placebo	084	17	V6 (WEEK 52)	371	22NOV2011	12:05	YES	NO	
	086	21	SCREENING	-24	04OCT2010	11:10	YES	NO	
			V1 (WEEK 0)	1	28OCT2010	16:45	YES	NO	
			V3 (WEEK 12)	83	18JAN2011	12:55	YES	NO	
			V4 (WEEK 24)	167	12APR2011	12:04	YES	YES	INTERMITTENT SINUS ARRHYTHMIA
			V5 (WEEK 36)	251	05JUL2011	12:02	YES	NO	
			V6 (WEEK 52)	363	25OCT2011	11:49	YES	YES	LEFT ANTERIOR HEMIBLOCK
	088	16	SCREENING	-9	30NOV2010	10:06	YES	NO	
			V1 (WEEK 0)	1	09DEC2010	9:00	YES	NO	
			V3 (WEEK 12)	83	01MAR2011	9:45	YES	NO	
			V4 (WEEK 24)	162	19MAY2011	9:35	YES	NO	
			V5 (WEEK 36)	264	29AUG2011	9:42	YES	NO	

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
ACI-91	002	1	V3 (WEEK 12) - V1 (WEEK 0)	4	12	0	-12	-3	-6	-50
			V4 (WEEK 24) - V1 (WEEK 0)	5	13	-3	-13	-2	-6	-58
			V5 (WEEK 36) - V1 (WEEK 0)	8	3	-3	-14	4	-2	-94
			V6 (WEEK 52) - V1 (WEEK 0)	4	-22	0	-5	1	0	-37
	004	1	V3 (WEEK 12) - V1 (WEEK 0)	6	-13	5	-18	1	-5	-93
			V3 (WEEK 12) - V1 (WEEK 0)	6	-13	5	-18	1	-5	-93
			V3 (WEEK 12) - V1 (WEEK 0)	6	-13	5	-18	1	-5	-93
			V3 (WEEK 12) - V1 (WEEK 0)	6	-13	5	-18	1	-5	-93
	006	2	V3 (WEEK 12) - V1 (WEEK 0)	-1	4	1	17	11	14	48
			V4 (WEEK 24) - V1 (WEEK 0)	-1	5	1	29	22	25	59
			V5 (WEEK 36) - V1 (WEEK 0)	-1	-2	-1	-1	-7	-6	16
			V6 (WEEK 52) - V1 (WEEK 0)	-4	2	-3	15	-2	2	56
	010	1	V3 (WEEK 12) - V1 (WEEK 0)	6	-14	-2	-74	-54	-64	-126
			V3 (WEEK 12) - V1 (WEEK 0)	6	-14	-2	-74	-54	-64	-126
			V3 (WEEK 12) - V1 (WEEK 0)	6	-14	-2	-74	-54	-64	-126
			V3 (WEEK 12) - V1 (WEEK 0)	6	-14	-2	-74	-54	-64	-126
	012	1	V3 (WEEK 12) - V1 (WEEK 0)	-7	0	4	15	-19	-8	206
			V4 (WEEK 24) - V1 (WEEK 0)	-7	-5	-4	18	-9	0	155
			V5 (WEEK 36) - V1 (WEEK 0)	3	8	1	3	15	12	-68
			V6 (WEEK 52) - V1 (WEEK 0)	4	1	3	-15	4	-1	-96
	014	4	V3 (WEEK 12) - V1 (WEEK 0)	3	-2	2	1	15	10	-70
			V4 (WEEK 24) - V1 (WEEK 0)	4	0	4	-4	8	4	-61
			V5 (WEEK 36) - V1 (WEEK 0)	-2	0	7	76	46	56	140
			V6 (WEEK 52) - V1 (WEEK 0)	2	-10	2	-16	-5	-9	-54

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
ACI-91	015	4	V3 (WEEK 12) - V1 (WEEK 0)	6	-4	-2	-24	20	6	-248
			V4 (WEEK 24) - V1 (WEEK 0)	3	3	5	-19	17	6	-213
			V5 (WEEK 36) - V1 (WEEK 0)	7	1	4	-26	20	5	-263
			V6 (WEEK 52) - V1 (WEEK 0)	3	9	2	-35	0	-11	-200
	017	5	V3 (WEEK 12) - V1 (WEEK 0)	-3	2	-1	-14	-26	-21	35
			V4 (WEEK 24) - V1 (WEEK 0)	0	0	0	13	15	15	-1
			V5 (WEEK 36) - V1 (WEEK 0)	9	-1	0	19	44	35	-66
			V6 (WEEK 52) - V1 (WEEK 0)	4						
	019	5	V3 (WEEK 12) - V1 (WEEK 0)	-2	24	8	13	10	11	16
			V4 (WEEK 24) - V1 (WEEK 0)	5	10	14	-4	10	5	-61
			V5 (WEEK 36) - V1 (WEEK 0)	3	-29	3	-21	-15	-17	-34
			V6 (WEEK 52) - V1 (WEEK 0)	11	-18	11	-16	16	4	-139
	023	4	V3 (WEEK 12) - V1 (WEEK 0)	20	-9	2	-36	46	19	-365
			V4 (WEEK 24) - V1 (WEEK 0)	9	1	-1	-40	5	-9	-226
			V5 (WEEK 36) - V1 (WEEK 0)	13	-9	3	-12	31	15	-241
			V6 (WEEK 52) - V1 (WEEK 0)	14	-15	9	-72	-21	-38	-259
	027	20	V3 (WEEK 12) - V1 (WEEK 0)	6	-4	-2	-17	0	-6	-75
			V4 (WEEK 24) - V1 (WEEK 0)	4	-2	1	-14	10	1	-101
			V5 (WEEK 36) - V1 (WEEK 0)	13	-9	2	-42	-5	-18	-163
			V6 (WEEK 52) - V1 (WEEK 0)	6	-9	1	-10	12	4	-89

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
ACI-91	030	8	V3 (WEEK 12) - V1 (WEEK 0)	4	23	2	-40	-29	-33	-46
			V4 (WEEK 24) - V1 (WEEK 0)	8	18	1	-41	-13	-22	-145
			V5 (WEEK 36) - V1 (WEEK 0)	5	24	1	-36	-20	-25	-76
			V6 (WEEK 52) - V1 (WEEK 0)	7	18	1	-70	-47	-54	-111
	032	8	V3 (WEEK 12) - V1 (WEEK 0)	-2	0	2	9	4	5	24
	033	9	V3 (WEEK 12) - V1 (WEEK 0)	3	8	0	16	10	8	-26
			V4 (WEEK 24) - V1 (WEEK 0)	-3	23	2	38	23	28	72
			V5 (WEEK 36) - V1 (WEEK 0)	15	22	-2	-30	18	2	-222
	042	12	V3 (WEEK 12) - V1 (WEEK 0)	-7	12	-3	8	-7	-1	66
			V4 (WEEK 24) - V1 (WEEK 0)	24	3	-7	-12	33	17	-169
			V5 (WEEK 36) - V1 (WEEK 0)	1	6	-7	9	11	10	-5
			V6 (WEEK 52) - V1 (WEEK 0)		9	-8	-5	-23	-16	70
	043	12	V3 (WEEK 12) - V1 (WEEK 0)	-17	-32	0	38	-23	-1	255
			V4 (WEEK 24) - V1 (WEEK 0)	-3	-15	-2	5	-21	-11	97
	046	11	V3 (WEEK 12) - V1 (WEEK 0)	0	29	3	-1	0	0	-5
			V4 (WEEK 24) - V1 (WEEK 0)	-1	17	5	25	29	29	-2
			V5 (WEEK 36) - V1 (WEEK 0)	8	8	3	-10	7	1	-65
			V6 (WEEK 52) - V1 (WEEK 0)	8	11	5	19	48	37	-79

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
ACI-91	048	11	V3 (WEEK 12) - V1 (WEEK 0)	8	1	-6	-16	16	6	-147
			V4 (WEEK 24) - V1 (WEEK 0)	-4	0	-8	13	5	8	41
			V5 (WEEK 36) - V1 (WEEK 0)	-7	9	-7	2	-13	-8	82
			V6 (WEEK 52) - V1 (WEEK 0)	-3	11	-6	-14	-17	-16	18
	050	21	V3 (WEEK 12) - V1 (WEEK 0)	2	9	-1	2	3	3	-11
			V4 (WEEK 24) - V1 (WEEK 0)	1	26	11	26	29	28	-18
			V5 (WEEK 36) - V1 (WEEK 0)	10	8	3	8	29	22	-107
			V6 (WEEK 52) - V1 (WEEK 0)	3	45	3	-3	17	10	-100
	052	21	V3 (WEEK 12) - V1 (WEEK 0)	-8	15	10	17	-16	-5	147
			V4 (WEEK 24) - V1 (WEEK 0)	-8	17	1	37	13	21	109
			V5 (WEEK 36) - V1 (WEEK 0)	-4	14	3	24	8	13	70
			V6 (WEEK 52) - V1 (WEEK 0)	3	-7	3	-4	4	1	-28
	055	5	V3 (WEEK 12) - V1 (WEEK 0)	7	-12	1	-15	10	1	-109
	057	1	V3 (WEEK 12) - V1 (WEEK 0)	7	4	2	-24	-31	-29	46
			V4 (WEEK 24) - V1 (WEEK 0)	2	0	3	-12	-1	-5	-58
	066	16	V3 (WEEK 12) - V1 (WEEK 0)		0	2	31	-4	9	180
	067	16	V3 (WEEK 12) - V1 (WEEK 0)	5	-16	-2	-14	-3	-7	-49

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
ACI-91	071	18	V3 (WEEK 12) - V1 (WEEK 0)	3	-2	4	-7	3	0	-50
			V4 (WEEK 24) - V1 (WEEK 0)	-5	5	5	15	-1	3	83
			V5 (WEEK 36) - V1 (WEEK 0)	5	-6	4	5	23	16	-91
			V6 (WEEK 52) - V1 (WEEK 0)	5	0	6	-11	7	1	-88
	080	13	V3 (WEEK 12) - V1 (WEEK 0)	-15	7	1	15	-30	-14	186
			V4 (WEEK 24) - V1 (WEEK 0)	-26	-1	7	62	-14	12	340
	081	17	V3 (WEEK 12) - V1 (WEEK 0)	2	-4	4	2	6	5	-19
			V4 (WEEK 24) - V1 (WEEK 0)	13	-43	-65	-45	-6	-20	-171
			V5 (WEEK 36) - V1 (WEEK 0)	-2	13	-3	-3	-1	-2	-13
			V6 (WEEK 52) - V1 (WEEK 0)	2	-2	-5	-1	7	4	-35
	083	17	V3 (WEEK 12) - V1 (WEEK 0)		6	-7	57	51	53	36
			V4 (WEEK 24) - V1 (WEEK 0)	-6	3	5	26	2	9	121
	087	16	V3 (WEEK 12) - V1 (WEEK 0)	4	-9	-2	1	13	10	-52
			V4 (WEEK 24) - V1 (WEEK 0)	2	-5	6	-9	-2	-4	-35
			V5 (WEEK 36) - V1 (WEEK 0)	-5	-9	1	37	21	26	83
			V6 (WEEK 52) - V1 (WEEK 0)	1	-20	11	32	31	32	12
	089	5	V3 (WEEK 12) - V1 (WEEK 0)	2	7	-1	-10	1	-2	-49
			V4 (WEEK 24) - V1 (WEEK 0)	-6	-5	0	4	-19	-11	121
			V5 (WEEK 36) - V1 (WEEK 0)	0	5	0	3	-3	-1	28

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
ACI-91	089	5	V6 (WEEK 52) - V1 (WEEK 0)	-5	3	-6	30	17	22	63
	093	17	V3 (WEEK 12) - V1 (WEEK 0)	1	5	-3	-15	-7	-10	-33
			V4 (WEEK 24) - V1 (WEEK 0)	-27	54	46	73	24	42	210
			V5 (WEEK 36) - V1 (WEEK 0)	-37	14	-4	39	-43	-13	345
	097	12	V3 (WEEK 12) - V1 (WEEK 0)	10	17	-5	-2	32	20	-189
Placebo	001	1	V3 (WEEK 12) - V1 (WEEK 0)	2	20	-19	-20	-44	-35	64
			V4 (WEEK 24) - V1 (WEEK 0)	-5	-37	-55	-18	-54	-41	110
			V5 (WEEK 36) - V1 (WEEK 0)	-7	-33	-53	-22	-67	-51	142
			V6 (WEEK 52) - V1 (WEEK 0)	-12	-16	-50	-15	-78	-56	221
	003	1	V3 (WEEK 12) - V1 (WEEK 0)	8	8	0	-17	5	-5	-149
			V4 (WEEK 24) - V1 (WEEK 0)	3	1	1	-12	-1	-7	-93
	005	2	V3 (WEEK 12) - V1 (WEEK 0)	-4	18	1	25	10	15	81
			V4 (WEEK 24) - V1 (WEEK 0)	-5	20	-2	37	23	27	77
			V5 (WEEK 36) - V1 (WEEK 0)	-2	9	-2	32	21	22	13
			V6 (WEEK 52) - V1 (WEEK 0)	1	20	1	31	39	36	-49
	009	1	V3 (WEEK 12) - V1 (WEEK 0)	-4	-5	2	13	-3	3	65
			V4 (WEEK 24) - V1 (WEEK 0)	-8	-13	3	11	-6	0	90
			V5 (WEEK 36) - V1 (WEEK 0)	-5	-7	3	11	-6	0	68

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
Placebo	009	1	V6 (WEEK 52) - V1 (WEEK 0)	-4	-1	1	6	-15	-7	83
	011	1	V3 (WEEK 12) - V1 (WEEK 0)	-14	-7	8	37	15	24	107
			V4 (WEEK 24) - V1 (WEEK 0)	6	-4	42	5	26	19	-63
			V5 (WEEK 36) - V1 (WEEK 0)	-1		41	34	36	36	15
			V6 (WEEK 52) - V1 (WEEK 0)	-14		41	48	30	38	90
	013	4	V3 (WEEK 12) - V1 (WEEK 0)	-9	4	0	21	-2	6	100
			V4 (WEEK 24) - V1 (WEEK 0)	-5	1	0	28	-14	1	184
			V5 (WEEK 36) - V1 (WEEK 0)	-12	1	-1	36	-2	11	166
			V6 (WEEK 52) - V1 (WEEK 0)	-9	13	0	13	-18	-7	137
	016	4	V3 (WEEK 12) - V1 (WEEK 0)	7	0	5	-36	-6	-17	-139
			V4 (WEEK 24) - V1 (WEEK 0)	-5	-4	0	-34	-37	-36	26
			V5 (WEEK 36) - V1 (WEEK 0)	5	-10	0	-47	-16	-27	-149
			V6 (WEEK 52) - V1 (WEEK 0)	7	-13	0	-58	-27	-39	-147
	018	5	V3 (WEEK 12) - V1 (WEEK 0)	0	-3	-7	-11	-13	-13	5
			V4 (WEEK 24) - V1 (WEEK 0)	-2	-3	-1	-19	-22	-25	19
			V5 (WEEK 36) - V1 (WEEK 0)	0	1	0	-8	-9	-9	-1
			V6 (WEEK 52) - V1 (WEEK 0)	-9	-4	-2	18	-16	-6	177
	024	4	V3 (WEEK 12) - V1 (WEEK 0)	6	-2	-3	-27	19	5	-218
			V4 (WEEK 24) - V1 (WEEK 0)	3	0	-4	-7	29	18	-176

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
Placebo	024	4	V5 (WEEK 36) - V1 (WEEK 0)	3	4	-7	-17	19	8	-173
			V6 (WEEK 52) - V1 (WEEK 0)	20	-1	-4	-25	29	11	-250
	028	20	V3 (WEEK 12) - V1 (WEEK 0)	6	-13	0	7	24	19	-60
			V4 (WEEK 24) - V1 (WEEK 0)	20	3	-1	-20	19	5	-148
			V5 (WEEK 36) - V1 (WEEK 0)	11	-19	0	-1	32	21	-118
			V6 (WEEK 52) - V1 (WEEK 0)	0	5	1	19	21	20	1
	029	8	V3 (WEEK 12) - V1 (WEEK 0)	-7	3	5	-17	-33	-27	67
			V4 (WEEK 24) - V1 (WEEK 0)	-7	1	4	-8	-17	-14	40
			V5 (WEEK 36) - V1 (WEEK 0)	-8	2	3	0	-25	-16	111
			V6 (WEEK 52) - V1 (WEEK 0)	-5	8	1	-27	-35	-32	26
	031	8	V3 (WEEK 12) - V1 (WEEK 0)	0	1	-2	5	26	19	-78
			V4 (WEEK 24) - V1 (WEEK 0)	10	4	-1	-2	-2	-3	-2
			V5 (WEEK 36) - V1 (WEEK 0)	-1	-8	-1	-28	-29	-30	-6
			V6 (WEEK 52) - V1 (WEEK 0)	-7	-5	3	10	-4	1	61
	034	9	V3 (WEEK 12) - V1 (WEEK 0)	5	-1	1	1	17	11	-64
			V4 (WEEK 24) - V1 (WEEK 0)	0	0	1	12	14	13	-5
			V5 (WEEK 36) - V1 (WEEK 0)	8	1	-1	12	38	29	-91
	041	12	V3 (WEEK 12) - V1 (WEEK 0)	3	3	7	1	62	41	-58
			V4 (WEEK 24) - V1 (WEEK 0)	5	12	10	-10	47	27	-47

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
Placebo	041	12	V5 (WEEK 36) - V1 (WEEK 0)	0	14	10	-9	50	30	-50
			V6 (WEEK 52) - V1 (WEEK 0)	-11	12	9	31	45	40	129
	044	12	V3 (WEEK 12) - V1 (WEEK 0)	2	-10	5	-11	20	10	-134
			V4 (WEEK 24) - V1 (WEEK 0)	2	-13	9	1	26	18	-108
			V5 (WEEK 36) - V1 (WEEK 0)	18	-46	11	-30	34	12	-257
			V6 (WEEK 52) - V1 (WEEK 0)	6	-15	13	10	50	37	-160
	045	11	V3 (WEEK 12) - V1 (WEEK 0)	3	3	-1	2	10	7	-39
			V4 (WEEK 24) - V1 (WEEK 0)	0	3	0	-7	-9	-8	12
			V5 (WEEK 36) - V1 (WEEK 0)	4	3	0	-24	-4	-11	-101
			V6 (WEEK 52) - V1 (WEEK 0)	-1	3	-1	-7	-11	-10	25
	047	11	V3 (WEEK 12) - V1 (WEEK 0)	-9	-1	1	19	-11	-1	150
			V4 (WEEK 24) - V1 (WEEK 0)	-5	0	0	9	-5	0	74
			V5 (WEEK 36) - V1 (WEEK 0)	2	2	12	-1	12	8	-60
			V6 (WEEK 52) - V1 (WEEK 0)	-7	4	9	26	5	12	102
	049	21	V3 (WEEK 12) - V1 (WEEK 0)	12	-2	2	-32	-2	-13	-128
			V4 (WEEK 24) - V1 (WEEK 0)	0	6	1	-19	-21	-20	1
			V5 (WEEK 36) - V1 (WEEK 0)	0	0	8	-29	-24	-25	-33
	051	21	V3 (WEEK 12) - V1 (WEEK 0)	1						
			V4 (WEEK 24) - V1 (WEEK 0)	17	8	-4	-33	17	-1	-210

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
Placebo	051	21	V5 (WEEK 36) - V1 (WEEK 0)	1	13	1	34	25	28	44
			V6 (WEEK 52) - V1 (WEEK 0)	14	17	1	-20	20	6	-171
	056	5	V3 (WEEK 12) - V1 (WEEK 0)	-1	5	2	14	5	7	46
			V4 (WEEK 24) - V1 (WEEK 0)	-5	4	-3	0	-15	-11	89
			V5 (WEEK 36) - V1 (WEEK 0)	3	1	-2	10	25	19	-80
			V6 (WEEK 52) - V1 (WEEK 0)	-7	3	-2	16	0	5	86
	058	1	V3 (WEEK 12) - V1 (WEEK 0)	-2	3	5	16	20	19	-18
			V4 (WEEK 24) - V1 (WEEK 0)	-1	-24	4	14	27	23	-54
	059	1	V3 (WEEK 12) - V1 (WEEK 0)	7	-3	0	62	106	91	-132
			V4 (WEEK 24) - V1 (WEEK 0)	4	1	-1	-24	16	2	-166
			V5 (WEEK 36) - V1 (WEEK 0)	-3	-5	1	-6	-3	-4	-13
	065	16	V3 (WEEK 12) - V1 (WEEK 0)	-30	27	1	65	-42	-7	547
			V4 (WEEK 24) - V1 (WEEK 0)	-25	23	1	109	18	48	420
	068	16	V3 (WEEK 12) - V1 (WEEK 0)	5	9	1	-11	9	3	-125
			V4 (WEEK 24) - V1 (WEEK 0)	11	9	1	-48	0	-16	-282
			V5 (WEEK 36) - V1 (WEEK 0)	10	-2	1	-20	21	8	-245
			V6 (WEEK 52) - V1 (WEEK 0)	19	5	0	-34	40	15	-405
	069	23	V3 (WEEK 12) - V1 (WEEK 0)	-1	7	1	9	3	5	27

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Listing 16.2.9.2.2: Electrocardiogram (ECG) 12-lead. Difference to baseline

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
Placebo	069	23	V4 (WEEK 24) - V1 (WEEK 0)	-4	-14	3	24	29	27	-16
			V5 (WEEK 36) - V1 (WEEK 0)	11	-7	2	-4	26	16	-128
	072	18	V3 (WEEK 12) - V1 (WEEK 0)	-6	9	-1	-7	-39	-30	168
			V4 (WEEK 24) - V1 (WEEK 0)	-4	19	-2	-17	-20	-18	14
			V5 (WEEK 36) - V1 (WEEK 0)	1	-9	-1	-17	-17	-17	2
			V6 (WEEK 52) - V1 (WEEK 0)	-4	6	1	-4	-13	-10	46
	079	13	V3 (WEEK 12) - V1 (WEEK 0)	-7	-11	3	2	-36	-23	197
			V4 (WEEK 24) - V1 (WEEK 0)	-11	6	-5	21	-33	-16	282
			V5 (WEEK 36) - V1 (WEEK 0)	4	16	-4	-18	-11	-13	-35
			V6 (WEEK 52) - V1 (WEEK 0)	-10	7	-4	17	-36	-19	282
			V7 (WEEK 56) - V1 (WEEK 0)	-5	-13	2	-33	-61	-52	148
	082	17	V3 (WEEK 12) - V1 (WEEK 0)	-1	15	3	16	11	12	4
			V4 (WEEK 24) - V1 (WEEK 0)	-4	1	1	18	10	13	20
			V5 (WEEK 36) - V1 (WEEK 0)	-8	0	0	4	-14	-8	69
			V6 (WEEK 52) - V1 (WEEK 0)	-2	15	1	12	18	16	-47
	084	17	V3 (WEEK 12) - V1 (WEEK 0)	-4	4	0	20	-1	6	107
			V4 (WEEK 24) - V1 (WEEK 0)	3	-6	-5	10	6	7	21
			V5 (WEEK 36) - V1 (WEEK 0)	-8	-24	-2	38	12	21	127
			V6 (WEEK 52) - V1 (WEEK 0)	-16	3	-3	67	3	21	280

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Treat- ment	Random No.	Site ID	Visit difference	HR [bpm]	PR mean [ms]	QRS mean [ms]	QT mean [ms]	QTcB mean [ms]	QTcF mean [ms]	RR mean [ms]
Placebo	086	21	V3 (WEEK 12) - V1 (WEEK 0)	0	8	-2	-31	-8	-16	-101
			V4 (WEEK 24) - V1 (WEEK 0)	1	11	-7	-40	-15	-24	-108
			V5 (WEEK 36) - V1 (WEEK 0)	13	26	-4	-68	-32	-44	-165
			V6 (WEEK 52) - V1 (WEEK 0)	6	12	6	-10	6	1	-70
	088	16	V4 (WEEK 24) - V1 (WEEK 0)	-4	0	10	24	21	22	19
			V5 (WEEK 36) - V1 (WEEK 0)	-6	1	11	19	8	12	49
			V3 (WEEK 12) - V1 (WEEK 0)	2	11	7	-18	-16	-16	-21

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	002	1	SCREENING	-7	16APR2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
			V1 (WEEK 0)	1	23APR2009	SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	85	16JUL2009	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	002	1	V3 (WEEK 12)	85	16JUL2009	SKIN	UNCHANGED	
			V4 (WEEK 24)	169	08OCT2009	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V5 (WEEK 36)	258	05JAN2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V6 (WEEK 52)	365	22APR2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	002	1	V6 (WEEK 52)	365	22APR2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V7 (WEEK 56)	393	20MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	004	1	SCREENING	-29	17JUN2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	16JUL2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	004	1	V1 (WEEK 0)	1	16JUL2009	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	92	15OCT2009	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	NOT DONE	PATIENT REFUSED
						EARS, NOSE, THROAT	NOT DONE	PATIENT REFUSED
						HEART	NOT DONE	PATIENT REFUSED
						CHEST, LUNGS	NOT DONE	PATIENT REFUSED
						ABDOMEN	NOT DONE	PATIENT REFUSED
						EXTREMITIES	NOT DONE	PATIENT REFUSED
						PERIPHERAL PULSES	NOT DONE	PATIENT REFUSED
						SKIN	NOT DONE	PATIENT REFUSED
						OTHER PHYSICAL CONDITIONS	NOT DONE	PATIENT REFUSED
	006	2	SCREENING	-32	25JAN2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	ABNORMAL	PRESBYACUSIS, HAS HEARING AIDS
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	006	2	SCREENING	-32	25JAN2010	OTHER PHYSICAL CONDITIONS	NORMAL	
						HEAD, EYES	UNCHANGED	
			V1 (WEEK 0)	1	26FEB2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	85	21MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V4 (WEEK 24)	169	13AUG2010	EXTREMITIES	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	006	2	V4 (WEEK 24)	169	13AUG2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	252	04NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	364	24FEB2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	390	22MAR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	006	2	V7 (WEEK 56)	390	22MAR2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	010	1	SCREENING	-26	25JUN2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
		V1 (WEEK 0)		1	21JUL2009	EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
		V3 (WEEK 12)		85	13OCT2009	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	010	1	V3 (WEEK 12)	85	13OCT2009	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	012	1	SCREENING	-32	17JUN2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	19JUL2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	012	1	V1 (WEEK 0)	1	19JUL2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	88	14OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	CHANGED	LUMBOISCHIALGIA RIGHT, RENEWED SINCE 13.10.2010
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	176	10JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V5 (WEEK 36)	257	01APR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	012	1	V5 (WEEK 36)	257	01APR2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V6 (WEEK 52)	361	14JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	396	18AUG2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	014	4	SCREENING	-26	07OCT2009	HEAD, EYES	ABNORMAL	LATERAL DEVIATION OF THE LEFT EYE ON FIXATION (STRABISMUS DIVERGENS)
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
		V1 (WEEK 0)		1	02NOV2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
		V3 (WEEK 12)		85	25JAN2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	014	4	V3 (WEEK 12)	85	25JAN2010	EXTREMITIES	CHANGED	BONE FRACTURE OF THE LEFT HIPPER LIMB
			V4 (WEEK 24)	172	22APR2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	CHANGED	DISTAL RADIUSFRACTURE LEFT SIDE REMISSION
			V5 (WEEK 36)	256	15JUL2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V6 (WEEK 52)	361	28OCT2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	014	4	V6 (WEEK 52)	361	28OCT2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V7 (WEEK 56)	396	02DEC2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
	015	4	SCREENING	-32	21JAN2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	015	4	SCREENING	-32	21JAN2010	SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	22FEB2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	85	17MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	162	02AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
ACI-91	015	4	V4 (WEEK 24)	162	02AUG2010	EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	NOT DONE				
			V5 (WEEK 36)	248	27OCT2010	HEAD, EYES	UNCHANGED				
						EARS, NOSE, THROAT	UNCHANGED				
						HEART	UNCHANGED				
						CHEST, LUNGS	UNCHANGED				
						ABDOMEN	UNCHANGED				
						EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	NOT DONE				
						V6 (WEEK 52)	365	21FEB2011	HEAD, EYES	UNCHANGED	
									EARS, NOSE, THROAT	UNCHANGED	
									HEART	UNCHANGED	
			CHEST, LUNGS	UNCHANGED							
			ABDOMEN	UNCHANGED							
			EXTREMITIES	UNCHANGED							
			PERIPHERAL PULSES	UNCHANGED							
			SKIN	UNCHANGED							
			V7 (WEEK 56)	394	22MAR2011	OTHER PHYSICAL CONDITIONS	NOT DONE				
						HEAD, EYES	UNCHANGED				
						EARS, NOSE, THROAT	UNCHANGED				
						HEART	UNCHANGED				

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
ACI-91	015	4	V7 (WEEK 56)	394	22MAR2011	CHEST, LUNGS	UNCHANGED				
						ABDOMEN	UNCHANGED				
						EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	NOT DONE				
	017	5	SCREENING	-22	14JUL2009	HEAD, EYES	NORMAL				
						EARS, NOSE, THROAT	NORMAL				
						HEART	NORMAL				
						CHEST, LUNGS	NORMAL				
						ABDOMEN	NORMAL				
						EXTREMITIES	ABNORMAL	VARIKOSIS LEFT LEG			
						PERIPHERAL PULSES	NORMAL				
						SKIN	NORMAL				
						OTHER PHYSICAL CONDITIONS	NORMAL				
						V1 (WEEK 0)	1	05AUG2009	HEAD, EYES	UNCHANGED	
									EARS, NOSE, THROAT	UNCHANGED	
									HEART	UNCHANGED	
		CHEST, LUNGS	UNCHANGED								
		ABDOMEN	UNCHANGED								
		EXTREMITIES	UNCHANGED								
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	CHANGED	INCREASED SWEATING			
						OTHER PHYSICAL CONDITIONS	UNCHANGED				

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ACI-91	017	5	V3 (WEEK 12)	85	28OCT2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V4 (WEEK 24)	169	20JAN2010	SKIN	CHANGED	PLANE REDDENING STERNUM
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V5 (WEEK 36)	252	13APR2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	CHANGED	NO REDDENING_ BACK TO NORMAL
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	017	5	V5 (WEEK 36)	252	13APR2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	364	03AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	CHANGED	SHOULDER PAIN 26.-30. JULI 2010
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	392	31AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	CHANGED	SHOULDER PAIN RESOLVED
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	019	5	SCREENING	-21	18NOV2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	019	5	SCREENING	-21	18NOV2009	CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
			V1 (WEEK 0)	1	09DEC2009	OTHER PHYSICAL CONDITIONS	NORMAL	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V3 (WEEK 12)	85	03MAR2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	168	25MAY2010	HEAD, EYES	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V3 (WEEK 12)	85	03MAR2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	019	5	V4 (WEEK 24)	168	25MAY2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	259	24AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	364	07DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	019	5	V6 (WEEK 52)	364	07DEC2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	399	11JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
	023	4	SCREENING	-19	01JUL2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	20JUL2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
ACI-91	023	4	V1 (WEEK 0)	1	20JUL2010	EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	NOT DONE				
			V3 (WEEK 12)	86	13OCT2010	HEAD, EYES	UNCHANGED				
						EARS, NOSE, THROAT	UNCHANGED				
						HEART	UNCHANGED				
						CHEST, LUNGS	UNCHANGED				
						ABDOMEN	UNCHANGED				
						EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	NOT DONE				
						V4 (WEEK 24)	177	12JAN2011	HEAD, EYES	UNCHANGED	
									EARS, NOSE, THROAT	UNCHANGED	
									HEART	UNCHANGED	
			CHEST, LUNGS	UNCHANGED							
			ABDOMEN	UNCHANGED							
			EXTREMITIES	UNCHANGED							
			PERIPHERAL PULSES	UNCHANGED							
			SKIN	UNCHANGED							
			V5 (WEEK 36)	245	21MAR2011	OTHER PHYSICAL CONDITIONS	NOT DONE				
						HEAD, EYES	UNCHANGED				
						EARS, NOSE, THROAT	UNCHANGED				
						HEART	UNCHANGED				

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	023	4	V5 (WEEK 36)	245	21MAR2011	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	364	18JUL2011	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V7 (WEEK 56)	388	11AUG2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	027	20	SCREENING	-21	30SEP2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	21OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	92	20JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	027	20	V3 (WEEK 12)	92	20JAN2011	SKIN	UNCHANGED	
			V4 (WEEK 24)	174	12APR2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	259	06JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	370	25OCT2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	027	20	V6 (WEEK 52)	370	25OCT2011	EXTREMITIES	UNCHANGED	ATOPIC DERMATITIS
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	CHANGED	
			V7 (WEEK 56)	407	01DEC2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	030	8	SCREENING	-7	18MAR2010	HEAD, EYES	ABNORMAL	MYOPIA
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	25MAR2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	030	8	V1 (WEEK 0)	1	25MAR2010	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	85	17JUN2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V4 (WEEK 24)	163	03SEP2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	030	8	V5 (WEEK 36)	253	02DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V6 (WEEK 52)	355	14MAR2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	383	11APR2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	030	8	V7 (WEEK 56)	383	11APR2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	032	8	SCREENING	-10	08NOV2010	HEAD, EYES	ABNORMAL	MYOPIA, WEAR GLASES
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	18NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	82	07FEB2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	032	8	V3 (WEEK 12)	82	07FEB2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	033	9	SCREENING	-7	28OCT2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
		V1 (WEEK 0)		1	04NOV2009	EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
		V3 (WEEK 12)		78	20JAN2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	033	9	V3 (WEEK 12)	78	20JAN2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V4 (WEEK 24)	169	21APR2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V5 (WEEK 36)	261	22JUL2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	033	9	V5 (WEEK 36)	261	22JUL2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	372	10NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	398	06DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	042	12	SCREENING	-29	16DEC2009	HEAD, EYES	ABNORMAL	VISUS CORRECTED WITH GLASSES
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	042	12	SCREENING	-29	16DEC2009	EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	14JAN2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V3 (WEEK 12)	126	19MAY2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	168	30JUN2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	042	12	V4 (WEEK 24)	168	30JUN2010	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	252	22SEP2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V6 (WEEK 52)	364	12JAN2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	391	08FEB2011	HEAD, EYES	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	042	12	V7 (WEEK 56)	391	08FEB2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	043	12	SCREENING	-28	21OCT2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	18NOV2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	043	12	V1 (WEEK 0)	1	18NOV2009	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	85	10FEB2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	176	12MAY2010	HEAD, EYES	CHANGED	RIGOR OF NECK, OCCIPITAL CICATRICE
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	CHANGED	RIGOR OF UPPER EXTREMETIES
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	CHANGED	HYPOKINESIA
			V6 (WEEK 52)	267	11AUG2010	HEAD, EYES	CHANGED	MASSIVE NECK RIGOR
						EARS, NOSE, THROAT	CHANGED	DRY THROAT WITH COVERED TONGUE, DYSPHAGIA
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	043	12	V6 (WEEK 52)	267	11AUG2010	CHEST, LUNGS	CHANGED	BRONCHIAL RESPIRATION
						ABDOMEN	UNCHANGED	
						EXTREMITIES	CHANGED	MASSIVE RIGOR OF ALL EXTREMETIES
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	CHANGED	DECLINE OF GENERAL CONDITION
	046	11	SCREENING	-28	14DEC2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
						HEAD, EYES	UNCHANGED	
EARS, NOSE, THROAT						UNCHANGED		
HEART						UNCHANGED		
CHEST, LUNGS						UNCHANGED		
ABDOMEN						UNCHANGED		
EXTREMITIES	UNCHANGED							
PERIPHERAL PULSES	UNCHANGED							
SKIN	UNCHANGED							

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	046	11	V1 (WEEK 0)	1	11JAN2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	87	07APR2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	CHANGED	HAEMATOMA SMALL ON NOSE
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V4 (WEEK 24)	178	07JUL2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	CHANGED	NO EDEMA ANYMORE
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	255	22SEP2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	046	11	V5 (WEEK 36)	255	22SEP2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	367	12JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
		V7 (WEEK 56)	393	07FEB2011	HEAD, EYES	UNCHANGED		
					EARS, NOSE, THROAT	UNCHANGED		
					HEART	UNCHANGED		
					CHEST, LUNGS	UNCHANGED		
					ABDOMEN	UNCHANGED		
					EXTREMITIES	UNCHANGED		
					PERIPHERAL PULSES	UNCHANGED		
					SKIN	UNCHANGED		
					OTHER PHYSICAL CONDITIONS	UNCHANGED		
	EARS, NOSE, THROAT				NORMAL			
	HEART				NORMAL			

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	048	11	SCREENING	-5	17NOV2010	CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	22NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
			V3 (WEEK 12)	86	15FEB2011	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
			V4 (WEEK 24)	176	16MAY2011	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	048	11	V4 (WEEK 24)	176	16MAY2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V5 (WEEK 36)	247	26JUL2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V6 (WEEK 52)	360	16NOV2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	048	11	V6 (WEEK 52)	360	16NOV2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	395	21DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
	050	21	SCREENING	-51	06SEP2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	27OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	050	21	V1 (WEEK 0)	1	27OCT2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	83	17JAN2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V4 (WEEK 24)	167	11APR2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	251	04JUL2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	050	21	V5 (WEEK 36)	251	04JUL2011	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	363	24OCT2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V7 (WEEK 56)	391	21NOV2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	052	21	SCREENING	-52	06SEP2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	28OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	82	17JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	052	21	V3 (WEEK 12)	82	17JAN2011	SKIN	UNCHANGED	
			V4 (WEEK 24)	166	11APR2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	250	04JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	362	24OCT2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	052	21	V6 (WEEK 52)	362	24OCT2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	390	21NOV2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	055	5	SCREENING	-21	08MAR2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	ABNORMAL	PAIN IN THE RIGHT SHOULDER
								AFTER FALL ONE WEEK AGO
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	29MAR2010	HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	055	5	V1 (WEEK 0)	1	29MAR2010	EARS, NOSE, THROAT	UNCHANGED	PAIN IN RIGHT SHOULDER DISAPPEARED
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	CHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V6 (WEEK 52)	30	27APR2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	057	1	SCREENING	-21	29JUL2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	057	1	SCREENING	-21	29JUL2010	EXTREMITIES	ABNORMAL	CUTANEOUS CHANGES BECAUSE OF PSORIASIS
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	19AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	82	08NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	170	04FEB2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	057	1	V4 (WEEK 24)	170	04FEB2011	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	066	16	SCREENING	-31	09AUG2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	09SEP2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	066	16	V1 (WEEK 0)	1	09SEP2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	83	30NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	067	16	SCREENING	-16	02NOV2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
						HEAD, EYES	UNCHANGED	
			V1 (WEEK 0)	1	18NOV2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	067	16	V1 (WEEK 0)	1	18NOV2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	69	25JAN2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	111	08MAR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	071	18	SCREENING	-20	20OCT2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	071	18	SCREENING	-20	20OCT2010	HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	ABNORMAL	SCAR THROAT = THYROID, RIGHT UPPER LEG
			V1 (WEEK 0)	1	09NOV2010	OTHER PHYSICAL CONDITIONS	NORMAL	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V3 (WEEK 12)	87	03FEB2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	CHANGED	CATARACT RIGHT EYE
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	071	18	V3 (WEEK 12)	87	03FEB2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	IMPROVEMENT
			V4 (WEEK 24)	177	04MAY2011	HEAD, EYES	CHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	253	19JUL2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	374	17NOV2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	071	18	V6 (WEEK 52)	374	17NOV2011	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
		V7 (WEEK 56)		392	05DEC2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	080	13	SCREENING	-10	08NOV2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
						V1 (WEEK 0)	1	18NOV2010
		EARS, NOSE, THROAT		UNCHANGED				
						HEART	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	080	13	V1 (WEEK 0)	1	18NOV2010	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	84	09FEB2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V6 (WEEK 52)	196	01JUN2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	081	17	SCREENING	-10	04OCT2010	HEAD, EYES	NORMAL	HYPAKUSIS
						EARS, NOSE, THROAT	ABNORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	14OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	89	10JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	SKIN	UNCHANGED	
			V4 (WEEK 24)	175	06APR2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	250	20JUN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	376	24OCT2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding				
ACI-91	081	17	V6 (WEEK 52)	376	24OCT2011	EXTREMITIES	UNCHANGED					
						PERIPHERAL PULSES	UNCHANGED					
						SKIN	UNCHANGED					
		17	V7 (WEEK 56)	405	22NOV2011	OTHER PHYSICAL CONDITIONS	UNCHANGED					
						HEAD, EYES	UNCHANGED					
						EARS, NOSE, THROAT	UNCHANGED					
						HEART	UNCHANGED					
						CHEST, LUNGS	UNCHANGED					
						ABDOMEN	UNCHANGED					
						EXTREMITIES	UNCHANGED					
	PERIPHERAL PULSES					UNCHANGED						
	SKIN					UNCHANGED						
	OTHER PHYSICAL CONDITIONS					UNCHANGED						
	083	17	SCREENING	-15	26OCT2010	HEAD, EYES	NORMAL					
						EARS, NOSE, THROAT	NORMAL					
						HEART	NORMAL					
						CHEST, LUNGS	NORMAL					
						ABDOMEN	NORMAL					
						EXTREMITIES	NORMAL					
						PERIPHERAL PULSES	NORMAL					
						SKIN	ABNORMAL	NEURODERMATITIS				
						OTHER PHYSICAL CONDITIONS	NORMAL					
						17	V1 (WEEK 0)	1	10NOV2010	HEAD, EYES	UNCHANGED	
										EARS, NOSE, THROAT	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	083	17	V1 (WEEK 0)	1	10NOV2010	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	85	02FEB2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V4 (WEEK 24)	168	26APR2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	083	17	V5 (WEEK 36)	258	25JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V6 (WEEK 52)	365	09NOV2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	392	06DEC2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	083	17	V7 (WEEK 56)	392	06DEC2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	087	16	SCREENING	-20	09NOV2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	29NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	81	17FEB2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	087	16	V3 (WEEK 12)	81	17FEB2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	169	16MAY2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V5 (WEEK 36)	255	10AUG2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
			V6 (WEEK 52)	365	28NOV2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	087	16	V6 (WEEK 52)	365	28NOV2011	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	395	28DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	089	5	SCREENING	-28	19OCT2010	HEAD, EYES	ABNORMAL	MYOPIA - 19 R, -21 L MACULA DEGENERATION, SKOTAN
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	089	5	SCREENING	-28	19OCT2010	SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	16NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	84	07FEB2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	168	02MAY2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	089	5	V4 (WEEK 24)	168	02MAY2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	252	25JUL2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
			V6 (WEEK 52)	364	14NOV2011	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V7 (WEEK 56)	394	14DEC2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
ACI-91	089	5	V7 (WEEK 56)	394	14DEC2011	CHEST, LUNGS	UNCHANGED				
						ABDOMEN	UNCHANGED				
						EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	UNCHANGED				
	093	17	SCREENING	-3	29NOV2010	HEAD, EYES	NORMAL				
						EARS, NOSE, THROAT	NORMAL				
						HEART	NORMAL				
						CHEST, LUNGS	NORMAL				
						ABDOMEN	NORMAL				
						EXTREMITIES	NORMAL				
						PERIPHERAL PULSES	NORMAL				
						SKIN	NORMAL				
						OTHER PHYSICAL CONDITIONS	NORMAL				
						V1 (WEEK 0)	1	02DEC2010	HEAD, EYES	UNCHANGED	
									EARS, NOSE, THROAT	UNCHANGED	
									HEART	UNCHANGED	
		CHEST, LUNGS	UNCHANGED								
		ABDOMEN	UNCHANGED								
		EXTREMITIES	UNCHANGED								
							PERIPHERAL PULSES	UNCHANGED			
							SKIN	UNCHANGED			
							OTHER PHYSICAL CONDITIONS	UNCHANGED			

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	093	17	V3 (WEEK 12)	86	25FEB2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
			V4 (WEEK 24)	173	23MAY2011	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
			V5 (WEEK 36)	258	16AUG2011	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	093	17	V5 (WEEK 36)	258	16AUG2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	370	06DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	392	28DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	097	12	SCREENING	-21	27OCT2010	HEAD, EYES	ABNORMAL	VISUS CORRECTION WITH GLASSES
						EARS, NOSE, THROAT	ABNORMAL	HYPACUSIS LEFT SIDE
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	097	12	SCREENING	-21	27OCT2010	ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	17NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	85	09FEB2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	CHANGED	HAEMATOMA LATERAL RIGHT TIGH
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
Placebo	001	1	SCREENING	-7	02APR2009	HEAD, EYES	ABNORMAL	HYPEROPIA BILATERAL

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	001	1	SCREENING	-7	02APR2009	EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	09APR2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	90	07JUL2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	001	1	V3 (WEEK 12)	90	07JUL2009	OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	162	17SEP2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	246	10DEC2009	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	365	08APR2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	001	1	V6 (WEEK 52)	365	08APR2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
		V7 (WEEK 56)		393	06MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
	003	1	SCREENING	-21	07MAY2009	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
		V1 (WEEK 0)		1	28MAY2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	003	1	V1 (WEEK 0)	1	28MAY2009	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	90	25AUG2009	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V4 (WEEK 24)	169	12NOV2009	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V5 (WEEK 36)	253	04FEB2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
Placebo	003	1	V5 (WEEK 36)	253	04FEB2010	EARS, NOSE, THROAT	UNCHANGED				
						HEART	UNCHANGED				
						CHEST, LUNGS	UNCHANGED				
						ABDOMEN	UNCHANGED				
						EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	NOT DONE				
	005	2	SCREENING	-16	19MAY2009	HEAD, EYES	NORMAL				
						EARS, NOSE, THROAT	NORMAL				
						HEART	NORMAL				
						CHEST, LUNGS	NORMAL				
						ABDOMEN	NORMAL				
						EXTREMITIES	NORMAL				
						PERIPHERAL PULSES	NORMAL				
						SKIN	NORMAL				
						OTHER PHYSICAL CONDITIONS	NORMAL				
						V1 (WEEK 0)	1	04JUN2009	HEAD, EYES	UNCHANGED	
									EARS, NOSE, THROAT	UNCHANGED	
									HEART	UNCHANGED	
									CHEST, LUNGS	UNCHANGED	
									ABDOMEN	UNCHANGED	
									EXTREMITIES	UNCHANGED	
									PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	005	2	V1 (WEEK 0)	1	04JUN2009	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	83	25AUG2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	168	18NOV2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	258	16FEB2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	005	2	V5 (WEEK 36)	258	16FEB2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	364	02JUN2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
		EARS, NOSE, THROAT				UNCHANGED		
		HEART				UNCHANGED		
		CHEST, LUNGS				UNCHANGED		
		ABDOMEN				UNCHANGED		
		EXTREMITIES				UNCHANGED		
		PERIPHERAL PULSES				UNCHANGED		
		SKIN				UNCHANGED		
		OTHER PHYSICAL CONDITIONS				UNCHANGED		
		V7 (WEEK 56)	400	08JUL2010	HEAD, EYES	UNCHANGED		
					EARS, NOSE, THROAT	UNCHANGED		
					HEART	UNCHANGED		
					CHEST, LUNGS	UNCHANGED		
					ABDOMEN	UNCHANGED		
					EXTREMITIES	UNCHANGED		
	PERIPHERAL PULSES				UNCHANGED			
SKIN	UNCHANGED							
OTHER PHYSICAL CONDITIONS	UNCHANGED							
009	1	SCREENING	-33	06AUG2009	HEAD, EYES	NORMAL		
					EARS, NOSE, THROAT	NORMAL		

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	009	1	SCREENING	-33	06AUG2009	HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
			V1 (WEEK 0)	1	08SEP2009	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	94	10DEC2009	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	009	1	V4 (WEEK 24)	178	04MAR2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	246	11MAY2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	361	03SEP2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding	
Placebo	009	1	V6 (WEEK 52)	361	03SEP2010	SKIN	UNCHANGED		
						OTHER PHYSICAL CONDITIONS	NOT DONE		
		V7 (WEEK 56)		389	01OCT2010	HEAD, EYES	UNCHANGED		
						EARS, NOSE, THROAT	UNCHANGED		
						HEART	UNCHANGED		
						CHEST, LUNGS	UNCHANGED		
						ABDOMEN	UNCHANGED		
						EXTREMITIES	UNCHANGED		
						PERIPHERAL PULSES	UNCHANGED		
						SKIN	UNCHANGED		
						OTHER PHYSICAL CONDITIONS	NOT DONE		
	011	1	SCREENING	-21	05NOV2009	HEAD, EYES	NORMAL		
						EARS, NOSE, THROAT	NORMAL		
						HEART	NORMAL		
						CHEST, LUNGS	NORMAL		
						ABDOMEN	NORMAL		
						EXTREMITIES	NORMAL		
						PERIPHERAL PULSES	NORMAL		
						SKIN	NORMAL		
						OTHER PHYSICAL CONDITIONS	NOT DONE		
		V1 (WEEK 0)		1	26NOV2009	HEAD, EYES	UNCHANGED		
						EARS, NOSE, THROAT	UNCHANGED		
						HEART	UNCHANGED		
						CHEST, LUNGS	UNCHANGED		

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	011	1	V1 (WEEK 0)	1	26NOV2009	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	85	18FEB2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						V4 (WEEK 24)	162	06MAY2010
			EARS, NOSE, THROAT	UNCHANGED				
			HEART	UNCHANGED				
			CHEST, LUNGS	UNCHANGED				
			ABDOMEN	UNCHANGED				
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						V5 (WEEK 36)	253	05AUG2010
			EARS, NOSE, THROAT	UNCHANGED				

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	011	1	V5 (WEEK 36)	253	05AUG2010	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	366	26NOV2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	397	27DEC2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	013	4	SCREENING	-30	17AUG2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
			V1 (WEEK 0)	1	16SEP2009	SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	85	09DEC2009	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	013	4	V3 (WEEK 12)	85	09DEC2009	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	170	04MAR2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V5 (WEEK 36)	247	20MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V6 (WEEK 52)	366	16SEP2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding	
Placebo	013	4	V6 (WEEK 52)	366	16SEP2010	EXTREMITIES	UNCHANGED		
						PERIPHERAL PULSES	UNCHANGED		
						SKIN	UNCHANGED		
		4	V7 (WEEK 56)	400	20OCT2010	OTHER PHYSICAL CONDITIONS	NOT DONE		
						HEAD, EYES	UNCHANGED		
						EARS, NOSE, THROAT	UNCHANGED		
						HEART	UNCHANGED		
						CHEST, LUNGS	UNCHANGED		
						ABDOMEN	UNCHANGED		
						EXTREMITIES	UNCHANGED		
	016	4	SCREENING	-28	01FEB2010	PERIPHERAL PULSES	UNCHANGED		
						SKIN	UNCHANGED		
						OTHER PHYSICAL CONDITIONS	NOT DONE		
						HEAD, EYES	ABNORMAL	VISUS DEFICIENCY ON THE LEFT EYE	
						EARS, NOSE, THROAT	NORMAL		
						HEART	NORMAL		
						CHEST, LUNGS	NORMAL		
						ABDOMEN	NORMAL		
						EXTREMITIES	NORMAL		
						PERIPHERAL PULSES	NORMAL		
						SKIN	NORMAL		
		4		1	01MAR2010	OTHER PHYSICAL CONDITIONS	NOT DONE		
						HEAD, EYES	UNCHANGED		
		4	V1 (WEEK 0)	1	01MAR2010	HEAD, EYES	UNCHANGED		
						HEAD, EYES	UNCHANGED		

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	016	4	V1 (WEEK 0)	1	01MAR2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V3 (WEEK 12)	80	19MAY2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V4 (WEEK 24)	162	09AUG2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	016	4	V4 (WEEK 24)	162	09AUG2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
			V5 (WEEK 36)	253	08NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	365	28FEB2011	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V7 (WEEK 56)	403	07APR2011	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	016	4	V7 (WEEK 56)	403	07APR2011	PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED CHANGED	ACCORDING TO EEG FINDING OF 28.2.2011 PAT. SEEMS TO HAVE FOCAL SEIZURES
	018	5	SCREENING	-20	03NOV2009	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	
			V1 (WEEK 0)	1	23NOV2009	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	86	16FEB2010	HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	018	5	V3 (WEEK 12)	86	16FEB2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	170	11MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	247	27JUL2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	018	5	V5 (WEEK 36)	247	27JUL2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	366	23NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	020	5	V7 (WEEK 56)	387	14DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			SCREENING	-26	27JAN2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	020	5	SCREENING	-26	27JAN2010	EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	22FEB2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	024	4	SCREENING	-31	16JUL2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	ABNORMAL	SCARS IN THE FACE, FRONT OF NOSE, FORHEAD
						HEART	ABNORMAL	RIGHT BUNDLE BRANCH BLOCK IN ECG
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	024	4	V1 (WEEK 0)	1	16AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	87	10NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	171	02FEB2011	HEAD, EYES	CHANGED	CATARACT SURGERY ON THE LEFT EYE NOV 2010
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	024	4	V4 (WEEK 24)	171	02FEB2011	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V5 (WEEK 36)	246	18APR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V6 (WEEK 52)	358	08AUG2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V7 (WEEK 56)	393	12SEP2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	024	4	V7 (WEEK 56)	393	12SEP2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	028	20	SCREENING	-8	18NOV2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	26NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	89	22FEB2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	028	20	V3 (WEEK 12)	89	22FEB2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V4 (WEEK 24)	180	24MAY2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V5 (WEEK 36)	273	25AUG2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	028	20	V5 (WEEK 36)	273	25AUG2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	364	24NOV2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
		8	V7 (WEEK 56)	390	20DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	029	8	SCREENING	-3	26JAN2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	029	8	SCREENING	-3	26JAN2010	EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
			V1 (WEEK 0)	1	29JAN2010	OTHER PHYSICAL CONDITIONS	NORMAL	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	82	20APR2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	158	05JUL2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	029	8	V4 (WEEK 24)	158	05JUL2010	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	245	30SEP2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V6 (WEEK 52)	369	01FEB2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	391	23FEB2011	HEAD, EYES	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	029	8	V7 (WEEK 56)	391	23FEB2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	031	8	SCREENING	-14	06MAY2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	20MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	031	8	V1 (WEEK 0)	1	20MAY2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	90	17AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	174	09NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	251	25JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	031	8	V5 (WEEK 36)	251	25JAN2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	363	17MAY2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	391	14JUN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	034	9	SCREENING	-22	24FEB2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	034	9	SCREENING	-22	24FEB2010	HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
			V1 (WEEK 0)	1	18MAR2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	83	08JUN2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	034	9	V4 (WEEK 24)	175	08SEP2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V5 (WEEK 36)	258	30NOV2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V6 (WEEK 52)	363	15MAR2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	034	9	V6 (WEEK 52)	363	15MAR2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V7 (WEEK 56)	399	20APR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	041	12	SCREENING	-16	23SEP2009	HEAD, EYES	ABNORMAL	CORRECTED VISUS DEFICIENCY
						EARS, NOSE, THROAT	ABNORMAL	AUDITORY DEFICIENCY - HEARING AID (BOTH SIDES)
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	ABNORMAL	ONYCHOMYCOSIS BOTH SIDES (FEET)
			V1 (WEEK 0)	1	09OCT2009	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	041	12	V1 (WEEK 0)	1	09OCT2009	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	89	05JAN2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V4 (WEEK 24)	167	24MAR2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	041	12	V5 (WEEK 36)	251	16JUN2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V6 (WEEK 52)	363	06OCT2010	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	392	04NOV2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	041	12	V7 (WEEK 56)	392	04NOV2010	SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED	
	044	12	SCREENING	-28	04NOV2009	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	ABNORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	MYOPIC
			V1 (WEEK 0)	1	02DEC2009	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	85	24FEB2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	044	12	V3 (WEEK 12)	85	24FEB2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	176	26MAY2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V5 (WEEK 36)	260	18AUG2010	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
			V6 (WEEK 52)	365	01DEC2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	044	12	V6 (WEEK 52)	365	01DEC2010	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	400	05JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	045	11	SCREENING	-14	07DEC2009	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	ABNORMAL	SWOLEN FINGER JOINTS
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	045	11	SCREENING V1 (WEEK 0)	-14 1	07DEC2009 21DEC2009	OTHER PHYSICAL CONDITIONS	NORMAL	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V3 (WEEK 12)	85	15MAR2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	CHANGED	RUSH LEFT LEG
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V4 (WEEK 24)	169	07JUN2010	OTHER PHYSICAL CONDITIONS	CHANGED	LIPOMA ON THE LEFT BACK SIDE
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	045	11	V4 (WEEK 24)	169	07JUN2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	260	06SEP2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	360	15DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	393	17JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	045	11	V7 (WEEK 56)	393	17JAN2011	ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
	047	11	SCREENING	-21	12JUL2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	ABNORMAL ABNORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	VISION REDUCED RIGHT EYE HYPACUSIS BOTH SIDES
			V1 (WEEK 0)	1	02AUG2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	80	20OCT2010	HEAD, EYES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	047	11	V3 (WEEK 12)	80	20OCT2010	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V4 (WEEK 24)	162	10JAN2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V5 (WEEK 36)	254	12APR2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	047	11	V5 (WEEK 36)	254	12APR2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	360	27JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V7 (WEEK 56)	393	29AUG2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	049	21	SCREENING	-51	06SEP2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	049	21	SCREENING	-51	06SEP2010	EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	27OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	84	18JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	168	12APR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	049	21	V4 (WEEK 24)	168	12APR2011	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	051	21	V5 (WEEK 36)	252	05JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	051	21	V1 (WEEK 0)	1	28OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	97	01FEB2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
			V4 (WEEK 24)	167	12APR2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	051	21	V4 (WEEK 24)	167	12APR2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	251	05JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	363	25OCT2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V7 (WEEK 56)	391	22NOV2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	051	21	V7 (WEEK 56)	391	22NOV2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	056	5	SCREENING	-21	31MAR2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	ABNORMAL	STOOPED POSTURE DUE TO LVB FRACTURE
			V1 (WEEK 0)	1	21APR2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V3 (WEEK 12)	84	13JUL2010	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	056	5	V3 (WEEK 12)	84	13JUL2010	EARS, NOSE, THROAT	UNCHANGED	15 CM LONG FRESH SCAR OVER SPINAL CORD AFTER SURGERY
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	CHANGED	
			V4 (WEEK 24)	168	05OCT2010	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V5 (WEEK 36)	259	04JAN2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	056	5	V5 (WEEK 36)	259	04JAN2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	364	19APR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
		1	V7 (WEEK 56)	393	18MAY2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	058	1	SCREENING	-21	06DEC2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	058	1	SCREENING	-21	06DEC2010	ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	27DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	93	29MAR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	166	10JUN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	058	1	V4 (WEEK 24)	166	10JUN2011	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	260	12SEP2011	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V6 (WEEK 52)	345	06DEC2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	

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Listing 16.2.9.3: Physical examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	058	1	V7 (WEEK 56)	380	10JAN2012	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
	059	1	SCREENING	-2	27DEC2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	
			V1 (WEEK 0)	1	29DEC2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	059	1	V1 (WEEK 0)	1	29DEC2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	93	31MAR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	161	07JUN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	CHANGED	HERPES ZOSTER
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V5 (WEEK 36)	254	08SEP2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	059	1	V5 (WEEK 36)	254	08SEP2011	ABDOMEN	UNCHANGED	TO NORMAL AFTER HERPES ZOSTER
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	CHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V6 (WEEK 52)	345	08DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	380	12JAN2012	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
065	16	SCREENING	-20	10AUG2010	HEAD, EYES	NORMAL		

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	065	16	SCREENING	-20	10AUG2010	EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	30AUG2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	85	22NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	065	16	V3 (WEEK 12)	85	22NOV2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
			V4 (WEEK 24)	141	17JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	068	16	SCREENING	-27	26OCT2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	22NOV2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
Placebo	068	16	V1 (WEEK 0)	1	22NOV2010	EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
			V3 (WEEK 12)	81	10FEB2011	OTHER PHYSICAL CONDITIONS	NOT DONE				
						HEAD, EYES	UNCHANGED				
						EARS, NOSE, THROAT	UNCHANGED				
						HEART	UNCHANGED				
						CHEST, LUNGS	UNCHANGED				
						ABDOMEN	UNCHANGED				
						EXTREMITIES	UNCHANGED				
						PERIPHERAL PULSES	UNCHANGED				
						SKIN	UNCHANGED				
						OTHER PHYSICAL CONDITIONS	UNCHANGED				
						V4 (WEEK 24)	163	03MAY2011	HEAD, EYES	UNCHANGED	
									EARS, NOSE, THROAT	UNCHANGED	
			HEART	UNCHANGED							
			CHEST, LUNGS	UNCHANGED							
			ABDOMEN	UNCHANGED							
			EXTREMITIES	UNCHANGED							
			PERIPHERAL PULSES	UNCHANGED							
			SKIN	UNCHANGED							
			OTHER PHYSICAL CONDITIONS	UNCHANGED							
			V5 (WEEK 36)	262	10AUG2011				HEAD, EYES	UNCHANGED	
									EARS, NOSE, THROAT	UNCHANGED	
									HEART	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	068	16	V5 (WEEK 36)	262	10AUG2011	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	372	28NOV2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V7 (WEEK 56)	414	09JAN2012	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	CHANGED	LOSS OF WEIGHT FROM 84 TO 76 KG

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	069	23	SCREENING	-13	24NOV2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	07DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	93	09MAR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	069	23	V3 (WEEK 12)	93	09MAR2011	SKIN	UNCHANGED	
			V4 (WEEK 24)	164	19MAY2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	261	24AUG2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	373	14DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	069	23	V6 (WEEK 52)	373	14DEC2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
			V7 (WEEK 56)	401	11JAN2012	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
	072	18	SCREENING	-20	01DEC2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	ABNORMAL	CATARACT RIGHT, LEFT LENS
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	ABNORMAL	SCAR 2. HIP OP
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V1 (WEEK 0)	1	21DEC2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	072	18	V1 (WEEK 0)	1	21DEC2010	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V3 (WEEK 12)	85	15MAR2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V4 (WEEK 24)	169	07JUN2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	072	18	V5 (WEEK 36)	262	08SEP2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V6 (WEEK 52)	360	15DEC2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	393	17JAN2012	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	072	18	V7 (WEEK 56)	393	17JAN2012	SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED	
	079	13	SCREENING	-18	19JUL2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	ABNORMAL NORMAL ABNORMAL NORMAL NORMAL NORMAL NORMAL NOT DONE	PRESBYOPIE SINCE ABOUT 20 YEARS BRADYCARDIA
			V1 (WEEK 0)	1	06AUG2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED NOT DONE	
			V3 (WEEK 12)	96	09NOV2010	HEAD, EYES EARS, NOSE, THROAT HEART	UNCHANGED UNCHANGED UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	079	13	V3 (WEEK 12)	96	09NOV2010	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V4 (WEEK 24)	175	27JAN2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V5 (WEEK 36)	249	11APR2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V6 (WEEK 52)	320	21JUN2011	HEAD, EYES	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
			V5 (WEEK 36)	249	11APR2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	079	13	V6 (WEEK 52)	320	21JUN2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V7 (WEEK 56)	348	19JUL2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
	082	17	SCREENING	-8	06OCT2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	082	17	SCREENING	-8	06OCT2010	SKIN	NORMAL	
			V1 (WEEK 0)	1	14OCT2010	OTHER PHYSICAL CONDITIONS	NOT DONE	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V3 (WEEK 12)	84	05JAN2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	175	06APR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	

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Listing 16.2.9.3: Physical examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	082	17	V4 (WEEK 24)	175	06APR2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	252	22JUN2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V6 (WEEK 52)	364	12OCT2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V7 (WEEK 56)	407	24NOV2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	082	17	V7 (WEEK 56)	407	24NOV2011	CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
	084	17	SCREENING	-9	08NOV2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	
						ABDOMEN	NORMAL	
						EXTREMITIES	ABNORMAL	ENDOPROTHESIS KNEE
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
					1	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	084	17	V3 (WEEK 12)	84	08FEB2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
			V4 (WEEK 24)	175	10MAY2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V5 (WEEK 36)	259	02AUG2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	084	17	V5 (WEEK 36)	259	02AUG2011	SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	371	22NOV2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V7 (WEEK 56)	394	15DEC2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
		HEAD, EYES				UNCHANGED		
		EARS, NOSE, THROAT				UNCHANGED		
		HEART				UNCHANGED		
		CHEST, LUNGS				UNCHANGED		
		ABDOMEN				UNCHANGED		
		EXTREMITIES				UNCHANGED		
		PERIPHERAL PULSES				UNCHANGED		
		SKIN				UNCHANGED		
		OTHER PHYSICAL CONDITIONS	UNCHANGED					
	086	21	SCREENING	-24	04OCT2010	HEAD, EYES	NORMAL	
						EARS, NOSE, THROAT	NORMAL	
						HEART	NORMAL	
						CHEST, LUNGS	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	086	21	SCREENING	-24	04OCT2010	ABDOMEN	NORMAL	
						EXTREMITIES	NORMAL	
						PERIPHERAL PULSES	NORMAL	
						SKIN	NORMAL	
						OTHER PHYSICAL CONDITIONS	NORMAL	
			V1 (WEEK 0)	1	28OCT2010	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V3 (WEEK 12)	83	18JAN2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
			V4 (WEEK 24)	167	12APR2011	EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	086	21	V4 (WEEK 24)	167	12APR2011	HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
			V5 (WEEK 36)	251	05JUL2011	OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V6 (WEEK 52)	363	25OCT2011	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	086	21	V7 (WEEK 56)	391	22NOV2011	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
	088	16	SCREENING	-9	30NOV2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES PERIPHERAL PULSES SKIN OTHER PHYSICAL CONDITIONS	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	
			V1 (WEEK 0)	1	09DEC2010	HEAD, EYES EARS, NOSE, THROAT HEART CHEST, LUNGS ABDOMEN EXTREMITIES	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	088	16	V1 (WEEK 0)	1	09DEC2010	PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	NOT DONE	
			V3 (WEEK 12)	83	01MAR2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V4 (WEEK 24)	162	19MAY2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V5 (WEEK 36)	264	29AUG2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	088	16	V5 (WEEK 36)	264	29AUG2011	ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
			V6 (WEEK 52)	376	19DEC2011	HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
			V7 (WEEK 56)	404	16JAN2012	EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	
						HEAD, EYES	UNCHANGED	
						EARS, NOSE, THROAT	UNCHANGED	
						HEART	UNCHANGED	
						CHEST, LUNGS	UNCHANGED	
						ABDOMEN	UNCHANGED	
						EXTREMITIES	UNCHANGED	
						PERIPHERAL PULSES	UNCHANGED	
						SKIN	UNCHANGED	
						OTHER PHYSICAL CONDITIONS	UNCHANGED	

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	002	1	SCREENING	-7	16APR2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	23APR2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	16JUL2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	002	1	V3 (WEEK 12)	85	16JUL2009	REFLEXES LE	UNCHANGED	
			V4 (WEEK 24)	169	08OCT2009	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	258	05JAN2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	365	22APR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	002	1	V6 (WEEK 52)	365	22APR2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	393	20MAY2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	004	1	SCREENING	-29	17JUN2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	004	1	SCREENING V1 (WEEK 0)	-29 1	17JUN2009 16JUL2009	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	92	15OCT2009	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NOT DONE	PATIENT REFUSED
						MUSCLE STRENGTH UE	NOT DONE	PATIENT REFUSED
						REFLEXES UE	NOT DONE	PATIENT REFUSED
						SENSATION UE	NOT DONE	PATIENT REFUSED
						CEREBELLAR FUNCTION UE	NOT DONE	PATIENT REFUSED
						MUSCLE STRENGTH LE	NOT DONE	PATIENT REFUSED
						REFLEXES LE	NOT DONE	PATIENT REFUSED
						SENSATION LE	NOT DONE	PATIENT REFUSED
						CEREBELLAR FUNCTION LE	NOT DONE	PATIENT REFUSED
	006	2	SCREENING	-32	25JAN2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	006	2	SCREENING	-32	25JAN2010	CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	ABNORMAL	ANKLE JERK REFLEX R>L
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	26FEB2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	21MAY2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	169	13AUG2010	CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	006	2	V4 (WEEK 24)	169	13AUG2010	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	252	04NOV2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V6 (WEEK 52)	364	24FEB2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	006	2	V6 (WEEK 52)	364	24FEB2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
		V7 (WEEK 56)		390	22MAR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	010	1	SCREENING	-26	25JUN2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
		V1 (WEEK 0)		1	21JUL2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	010	1	V1 (WEEK 0)	1	21JUL2009	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	13OCT2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	012	1	SCREENING	-32	17JUN2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	ABNORMAL	ASR RIGHT/LEFT NEGATIVE
						SENSATION LE	ABNORMAL	VIBRATION 0/8 BIMALLEOLAER

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	012	1	SCREENING V1 (WEEK 0)	-32 1	17JUN2010 19JUL2010	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V3 (WEEK 12)	88	14OCT2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	176	10JAN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	012	1	V4 (WEEK 24)	176	10JAN2011	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	257	01APR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	361	14JUL2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	396	18AUG2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	012	1	V7 (WEEK 56)	396	18AUG2011	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	014	4	SCREENING	-26	07OCT2009	CRANIAL NERVES	ABNORMAL	STRABISMUS DIVERGENS WITHOUT DIPLOPIE IMAGES
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
		V1 (WEEK 0)	1	02NOV2009	CRANIAL NERVES	UNCHANGED		
					MUSCLE STRENGTH UE	UNCHANGED		
					REFLEXES UE	UNCHANGED		
					SENSATION UE	UNCHANGED		
					CEREBELLAR FUNCTION UE	UNCHANGED		
					MUSCLE STRENGTH LE	UNCHANGED		

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	014	4	V1 (WEEK 0)	1	02NOV2009	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	25JAN2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	172	22APR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	256	15JUL2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	014	4	V5 (WEEK 36)	256	15JUL2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	361	28OCT2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	396	02DEC2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	015	4	SCREENING	-32	21JAN2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	22FEB2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	17MAY2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	015	4	V3 (WEEK 12)	85	17MAY2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	162	02AUG2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	248	27OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	365	21FEB2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding	
ACI-91	015	4	V6 (WEEK 52)	365	21FEB2011	SENSATION UE	UNCHANGED		
						CEREBELLAR FUNCTION UE	UNCHANGED		
						MUSCLE STRENGTH LE	UNCHANGED		
						REFLEXES LE	UNCHANGED		
						SENSATION LE	UNCHANGED		
						CEREBELLAR FUNCTION LE	UNCHANGED		
		V7 (WEEK 56)	394	22MAR2011		CRANIAL NERVES	UNCHANGED		
						MUSCLE STRENGTH UE	UNCHANGED		
						REFLEXES UE	UNCHANGED		
						SENSATION UE	UNCHANGED		
						CEREBELLAR FUNCTION UE	UNCHANGED		
						MUSCLE STRENGTH LE	UNCHANGED		
	017	5	SCREENING	-22	14JUL2009	REFLEXES LE	UNCHANGED		
						SENSATION LE	UNCHANGED		
						CEREBELLAR FUNCTION LE	UNCHANGED		
						CRANIAL NERVES	NORMAL		
						MUSCLE STRENGTH UE	NORMAL		
						REFLEXES UE	NORMAL		
						SENSATION UE	NORMAL		
						CEREBELLAR FUNCTION UE	ABNORMAL	SLIGHTY TREMOR BOTH HANDS, FINGER NOSE ATTEMPT SLIGHTLY DYSMETRIA	
						MUSCLE STRENGTH LE	NORMAL		

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	017	5	SCREENING	-22	14JUL2009	REFLEXES LE SENSATION LE	NORMAL ABNORMAL	PALLHYPAESTHESIA BOTH LEGS, LEFT MALLEOLUS 2/8, RIGHT MALLEOLUS 4/8
			V1 (WEEK 0)	1	05AUG2009	CEREBELLAR FUNCTION LE CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	NORMAL UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	85	28OCT2009	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V4 (WEEK 24)	169	20JAN2010	CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	017	5	V4 (WEEK 24)	169	20JAN2010	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	252	13APR2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V6 (WEEK 52)	364	03AUG2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	017	5	V6 (WEEK 52)	364	03AUG2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	392	31AUG2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
	019	5	SCREENING	-21	18NOV2009	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
			V1 (WEEK 0)	1	09DEC2009	REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	019	5	V1 (WEEK 0)	1	09DEC2009	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	85	03MAR2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V4 (WEEK 24)	168	25MAY2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	019	5	V5 (WEEK 36)	259	24AUG2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V6 (WEEK 52)	364	07DEC2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V7 (WEEK 56)	399	11JAN2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	019	5	V7 (WEEK 56)	399	11JAN2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	023	4	SCREENING	-19	01JUL2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	ABNORMAL	HYPESTHESIA ON THE LEFT HAND (FINGER I+II) DUE DISCUSPROLAPS C5/C6
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V1 (WEEK 0)	1	20JUL2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	023	4	V3 (WEEK 12)	86	13OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V4 (WEEK 24)	177	12JAN2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V5 (WEEK 36)	245	21MAR2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding	
ACI-91	023	4	V5 (WEEK 36)	245	21MAR2011	REFLEXES LE	UNCHANGED		
						SENSATION LE	UNCHANGED		
						CEREBELLAR FUNCTION LE	UNCHANGED		
			V6 (WEEK 52)	364	18JUL2011	CRANIAL NERVES	UNCHANGED		
					MUSCLE STRENGTH UE	UNCHANGED			
					REFLEXES UE	UNCHANGED			
					SENSATION UE	UNCHANGED			
					CEREBELLAR FUNCTION UE	UNCHANGED			
					MUSCLE STRENGTH LE	UNCHANGED			
					REFLEXES LE	UNCHANGED			
					SENSATION LE	UNCHANGED			
					CEREBELLAR FUNCTION LE	UNCHANGED			
		V7 (WEEK 56)	388	11AUG2011	CRANIAL NERVES	UNCHANGED			
					MUSCLE STRENGTH UE	UNCHANGED			
					REFLEXES UE	UNCHANGED			
					SENSATION UE	UNCHANGED			
					CEREBELLAR FUNCTION UE	UNCHANGED			
					MUSCLE STRENGTH LE	UNCHANGED			
					REFLEXES LE	UNCHANGED			
					SENSATION LE	UNCHANGED			
					CEREBELLAR FUNCTION LE	UNCHANGED			
		027	20	SCREENING	-21	30SEP2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL		

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	027	20	SCREENING	-21	30SEP2010	REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
			V1 (WEEK 0)	1	21OCT2010	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
			V3 (WEEK 12)	92	20JAN2011	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	027	20	V3 (WEEK 12)	92	20JAN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	174	12APR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	259	06JUL2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	370	25OCT2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	027	20	V6 (WEEK 52)	370	25OCT2011	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	407	01DEC2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	030	8	SCREENING	-7	18MAR2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	ABNORMAL	ATAXIA RIGHT HAND
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	25MAR2010	CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	030	8	V1 (WEEK 0)	1	25MAR2010	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V3 (WEEK 12)	85	17JUN2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	163	03SEP2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	CHANGED	HYPOESTHESIA RIGHT ARM
						CEREBELLAR FUNCTION UE	CHANGED	ATAXIA RIGHT ARM
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	030	8	V4 (WEEK 24)	163	03SEP2010	SENSATION LE	UNCHANGED	NORMAL
			V5 (WEEK 36)	253	02DEC2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V6 (WEEK 52)	355	14MAR2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	CHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	383	11APR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	030	8	V7 (WEEK 56)	383	11APR2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	032	8	SCREENING	-10	08NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	18NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	032	8	V3 (WEEK 12)	82	07FEB2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	033	9	SCREENING	-7	28OCT2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	04NOV2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	033	9	V1 (WEEK 0)	1	04NOV2009	MUSCLE STRENGTH LE	UNCHANGED	
			V3 (WEEK 12)	78	20JAN2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	169	21APR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	261	22JUL2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	033	9	V5 (WEEK 36)	261	22JUL2010	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V6 (WEEK 52)	372	10NOV2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	398	06DEC2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	033	9	V7 (WEEK 56)	398	06DEC2010	CEREBELLAR FUNCTION LE	UNCHANGED	
	042	12	SCREENING	-29	16DEC2009	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	NORMAL NORMAL NORMAL NORMAL ABNORMAL NORMAL NORMAL NORMAL ABNORMAL	ATAXIA HAND-NOSE ATAXIA
			V1 (WEEK 0)	1	14JAN2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	126	19MAY2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	042	12	V3 (WEEK 12)	126	19MAY2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	168	30JUN2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	252	22SEP2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	364	12JAN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	042	12	V6 (WEEK 52)	364	12JAN2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		V7 (WEEK 56)	391	08FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED		
					CRANIAL NERVES	UNCHANGED		
					MUSCLE STRENGTH UE	UNCHANGED		
					REFLEXES UE	UNCHANGED		
					SENSATION UE	UNCHANGED		
					CEREBELLAR FUNCTION UE	UNCHANGED		
					MUSCLE STRENGTH LE	UNCHANGED		
			REFLEXES LE	UNCHANGED				
			SENSATION LE	UNCHANGED				
			CEREBELLAR FUNCTION LE	UNCHANGED				
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
CEREBELLAR FUNCTION UE	NORMAL							
MUSCLE STRENGTH LE	NORMAL							

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	043	12	SCREENING	-28	21OCT2009	REFLEXES LE	ABNORMAL	ASR BOTH (LEFT + RIGHT)
								NEGATIVE
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	18NOV2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	10FEB2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	176	12MAY2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	043	12	V4 (WEEK 24)	176	12MAY2010	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	CHANGED	NO COOPERATION BY PATIENT
						REFLEXES UE	UNCHANGED	
	046	11	SCREENING	-28	14DEC2009	SENSATION UE	CHANGED	NO COOPERATION BY PATIENT
						CEREBELLAR FUNCTION UE	NOT DONE	
						MUSCLE STRENGTH LE	NOT DONE	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	NOT DONE	
						CEREBELLAR FUNCTION LE	NOT DONE	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	046	11	SCREENING	-28	14DEC2009	SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	11JAN2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	87	07APR2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	178	07JUL2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	046	11	V4 (WEEK 24)	178	07JUL2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	255	22SEP2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	367	12JAN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	393	07FEB2011	CRANIAL NERVES	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	046	11	V7 (WEEK 56)	393	07FEB2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	048	11	SCREENING	-5	17NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	22NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	048	11	V1 (WEEK 0)	1	22NOV2010	REFLEXES LE	UNCHANGED	
			V3 (WEEK 12)	86	15FEB2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	176	16MAY2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	247	26JUL2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	048	11	V5 (WEEK 36)	247	26JUL2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	360	16NOV2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	395	21DEC2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	050	21	SCREENING	-51	06SEP2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	27OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	83	17JAN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	050	21	V3 (WEEK 12)	83	17JAN2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	167	11APR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	251	04JUL2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	363	24OCT2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	050	21	V6 (WEEK 52)	363	24OCT2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	391	21NOV2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	052	21	SCREENING	-52	06SEP2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	052	21	SCREENING V1 (WEEK 0)	-52 1	06SEP2010 28OCT2010	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V3 (WEEK 12)	82	17JAN2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	166	11APR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	052	21	V4 (WEEK 24)	166	11APR2011	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	250	04JUL2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V6 (WEEK 52)	362	24OCT2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V7 (WEEK 56)	390	21NOV2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
ACI-91	052	21	V7 (WEEK 56)	390	21NOV2011	REFLEXES UE	UNCHANGED				
						SENSATION UE	UNCHANGED				
						CEREBELLAR FUNCTION UE	UNCHANGED				
						MUSCLE STRENGTH LE	UNCHANGED				
						REFLEXES LE	UNCHANGED				
						SENSATION LE	UNCHANGED				
						CEREBELLAR FUNCTION LE	UNCHANGED				
	055	5	SCREENING	-21	08MAR2010	CRANIAL NERVES	NORMAL				
						MUSCLE STRENGTH UE	NORMAL				
						REFLEXES UE	NORMAL				
						SENSATION UE	NORMAL				
						CEREBELLAR FUNCTION UE	NORMAL				
						MUSCLE STRENGTH LE	NORMAL				
						REFLEXES LE	NORMAL				
						SENSATION LE	NORMAL				
						CEREBELLAR FUNCTION LE	NORMAL				
						V1 (WEEK 0)	1	29MAR2010	CRANIAL NERVES	UNCHANGED	
									MUSCLE STRENGTH UE	UNCHANGED	
									REFLEXES UE	UNCHANGED	
									SENSATION UE	UNCHANGED	
									CEREBELLAR FUNCTION UE	UNCHANGED	
									MUSCLE STRENGTH LE	UNCHANGED	
									REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	055	5	V1 (WEEK 0)	1	29MAR2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	30	27APR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
	057	1	SCREENING	-21	29JUL2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
			V1 (WEEK 0)	1	19AUG2010	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding			
ACI-91	057	1	V1 (WEEK 0)	1	19AUG2010	SENSATION UE	UNCHANGED				
						CEREBELLAR FUNCTION UE	UNCHANGED				
						MUSCLE STRENGTH LE	UNCHANGED				
						REFLEXES LE	UNCHANGED				
			V3 (WEEK 12)	82	08NOV2010	SENSATION LE	UNCHANGED				
						CEREBELLAR FUNCTION LE	UNCHANGED				
						CRANIAL NERVES	UNCHANGED				
						MUSCLE STRENGTH UE	UNCHANGED				
						REFLEXES UE	UNCHANGED				
						SENSATION UE	UNCHANGED				
						CEREBELLAR FUNCTION UE	UNCHANGED				
						MUSCLE STRENGTH LE	UNCHANGED				
						REFLEXES LE	UNCHANGED				
						SENSATION LE	UNCHANGED				
						V4 (WEEK 24)	170	04FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED	
									CRANIAL NERVES	UNCHANGED	
			MUSCLE STRENGTH UE	UNCHANGED							
			REFLEXES UE	UNCHANGED							
			SENSATION UE	UNCHANGED							
			CEREBELLAR FUNCTION UE	UNCHANGED							
			MUSCLE STRENGTH LE	UNCHANGED							
			REFLEXES LE	UNCHANGED							
						SENSATION LE	UNCHANGED				
						CEREBELLAR FUNCTION LE	UNCHANGED				

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	066	16	SCREENING	-31	09AUG2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	09SEP2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	83	30NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	066	16	V3 (WEEK 12)	83	30NOV2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	067	16	SCREENING	-16	02NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	ABNORMAL	ACHILLES TENDON REFLEX (RIGHT) ABSENCE -> AT KNOWN L5/S1-SYNDROME WEAKNESS IN EXTENSION OF EXTENSION OF RIGHT FOOT
						REFLEXES LE	ABNORMAL	SEE 031) MUSCLE / STRENGTH: ACHILLES TENDON REFLEX ABSENCE (RIGHT)
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	18NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	067	16	V1 (WEEK 0)	1	18NOV2010	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		V6 (WEEK 52)				CEREBELLAR FUNCTION LE	UNCHANGED	
				69	25JAN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		V7 (WEEK 56)				CEREBELLAR FUNCTION LE	UNCHANGED	
				111	08MAR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
	071	18	SCREENING	-20	20OCT2010	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	071	18	SCREENING	-20	20OCT2010	MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	09NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	87	03FEB2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	071	18	V3 (WEEK 12)	87	03FEB2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	177	04MAY2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	253	19JUL2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	374	17NOV2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	071	18	V6 (WEEK 52)	374	17NOV2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		V7 (WEEK 56)		392	05DEC2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	080	13	SCREENING	-10	08NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	ABNORMAL	ASR LOW BOTH SIDES
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	080	13	V1 (WEEK 0)	1	18NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V3 (WEEK 12)	84	09FEB2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V6 (WEEK 52)	196	01JUN2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	080	13	V6 (WEEK 52)	196	01JUN2011	REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED	
	081	17	SCREENING	-10	04OCT2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	
			V1 (WEEK 0)	1	14OCT2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	89	10JAN2011	CRANIAL NERVES MUSCLE STRENGTH UE	UNCHANGED UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	175	06APR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	250	20JUN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	081	17	V5 (WEEK 36)	250	20JUN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	376	24OCT2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	405	22NOV2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	083	17	SCREENING	-15	26OCT2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	083	17	SCREENING	-15	26OCT2010	CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
			V1 (WEEK 0)	1	10NOV2010	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	85	02FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	168	26APR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	083	17	V4 (WEEK 24)	168	26APR2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	258	25JUL2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V6 (WEEK 52)	365	09NOV2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding	
ACI-91	083	17	V6 (WEEK 52)	365	09NOV2011	SENSATION LE	UNCHANGED		
						CEREBELLAR FUNCTION LE	UNCHANGED		
		V7 (WEEK 56)		392	06DEC2011	CRANIAL NERVES	UNCHANGED		
						MUSCLE STRENGTH UE	UNCHANGED		
						REFLEXES UE	UNCHANGED		
						SENSATION UE	UNCHANGED		
						CEREBELLAR FUNCTION UE	UNCHANGED		
						MUSCLE STRENGTH LE	UNCHANGED		
						REFLEXES LE	UNCHANGED		
						SENSATION LE	UNCHANGED		
						CEREBELLAR FUNCTION LE	UNCHANGED		
	087	16	SCREENING	-20	09NOV2010	CRANIAL NERVES	NORMAL		
						MUSCLE STRENGTH UE	NORMAL		
						REFLEXES UE	NORMAL		
						SENSATION UE	NORMAL		
						CEREBELLAR FUNCTION UE	NORMAL		
						MUSCLE STRENGTH LE	NORMAL		
						REFLEXES LE	NORMAL		
						SENSATION LE	NORMAL		
						CEREBELLAR FUNCTION LE	NORMAL		
		V1 (WEEK 0)		1	29NOV2010	CRANIAL NERVES	UNCHANGED		
						MUSCLE STRENGTH UE	UNCHANGED		
						REFLEXES UE	UNCHANGED		

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	087	16	V1 (WEEK 0)	1	29NOV2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V3 (WEEK 12)	81	17FEB2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V4 (WEEK 24)	169	16MAY2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	087	16	V5 (WEEK 36)	255	10AUG2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V6 (WEEK 52)	365	28NOV2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V7 (WEEK 56)	395	28DEC2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	087	16	V7 (WEEK 56)	395	28DEC2011	REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED	
	089	5	SCREENING	-28	19OCT2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	ABNORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	FACIAL ASYMMETRIA NO PARESIS
			V1 (WEEK 0)	1	16NOV2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	84	07FEB2011	CRANIAL NERVES MUSCLE STRENGTH UE	UNCHANGED UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	089	5	V3 (WEEK 12)	84	07FEB2011	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	168	02MAY2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	252	25JUL2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	089	5	V5 (WEEK 36)	252	25JUL2011	CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	364	14NOV2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	394	14DEC2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	093	17	SCREENING	-3	29NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	093	17	SCREENING	-3	29NOV2010	CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
			V1 (WEEK 0)	1	02DEC2010	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	86	25FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	173	23MAY2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	093	17	V4 (WEEK 24)	173	23MAY2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	258	16AUG2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V6 (WEEK 52)	370	06DEC2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	093	17	V6 (WEEK 52)	370	06DEC2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
		V7 (WEEK 56)		392	28DEC2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	097	12	SCREENING	-21	27OCT2010	CRANIAL NERVES	ABNORMAL	DYSFUNCTION OF NERVUS OCULOMOTORIS RIGHT SIDE
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	ABNORMAL	LIGHTLY ACCENTUATED RIGHT SIDE
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	ABNORMAL	LIGHTLY ACCENTUATED RIGHT SIDE
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
			V1 (WEEK 0)	1	17NOV2010			

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
ACI-91	097	12	V1 (WEEK 0)	1	17NOV2010	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V3 (WEEK 12)	85	09FEB2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
Placebo	001	1	SCREENING	-7	02APR2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	001	1	SCREENING	-7	02APR2009	SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	09APR2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	90	07JUL2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	162	17SEP2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	001	1	V4 (WEEK 24)	162	17SEP2009	CEREBELLAR FUNCTION UE	UNCHANGED	
			MUSCLE STRENGTH LE		UNCHANGED			
			REFLEXES LE		UNCHANGED			
			SENSATION LE		UNCHANGED			
			V5 (WEEK 36)	246	10DEC2009	CEREBELLAR FUNCTION LE	UNCHANGED	
			CRANIAL NERVES		UNCHANGED			
			MUSCLE STRENGTH UE		UNCHANGED			
			REFLEXES UE		UNCHANGED			
			SENSATION UE		UNCHANGED			
			CEREBELLAR FUNCTION UE		UNCHANGED			
			MUSCLE STRENGTH LE		UNCHANGED			
			REFLEXES LE		UNCHANGED			
			SENSATION LE		UNCHANGED			
			V6 (WEEK 52)	365	08APR2010	CEREBELLAR FUNCTION LE	UNCHANGED	
			CRANIAL NERVES		UNCHANGED			
			MUSCLE STRENGTH UE		UNCHANGED			
			REFLEXES UE		UNCHANGED			
			SENSATION UE		UNCHANGED			
			CEREBELLAR FUNCTION UE		UNCHANGED			
			MUSCLE STRENGTH LE		UNCHANGED			
			REFLEXES LE		UNCHANGED			
			SENSATION LE		UNCHANGED			
			V7 (WEEK 56)	393	06MAY2010	CEREBELLAR FUNCTION LE	UNCHANGED	
			CRANIAL NERVES		UNCHANGED			

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	001	1	V7 (WEEK 56)	393	06MAY2010	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	003	1	SCREENING	-21	07MAY2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	28MAY2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	003	1	V1 (WEEK 0)	1	28MAY2009	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	90	25AUG2009	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	169	12NOV2009	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	253	04FEB2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	003	1	V5 (WEEK 36)	253	04FEB2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	005	2	SCREENING	-16	19MAY2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	04JUN2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	005	2	V1 (WEEK 0)	1	04JUN2009	CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	83	25AUG2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	168	18NOV2009	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	258	16FEB2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	005	2	V5 (WEEK 36)	258	16FEB2010	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	364	02JUN2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
		V7 (WEEK 56)		400	08JUL2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
	009	1	SCREENING	-33	06AUG2009	CRANIAL NERVES	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	009	1	SCREENING	-33	06AUG2009	MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	ABNORMAL	ASR NEGATIVE LEFT / RIGHT
						SENSATION LE	ABNORMAL	PALLHYPAESTHESIA BIMALLEOLAR
						CEREBELLAR FUNCTION LE	NORMAL	
		V1 (WEEK 0)	1	08SEP2009		CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
		V3 (WEEK 12)	94	10DEC2009		CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	009	1	V3 (WEEK 12)	94	10DEC2009	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	178	04MAR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	246	11MAY2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	361	03SEP2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	009	1	V6 (WEEK 52)	361	03SEP2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	389	01OCT2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	011	1	SCREENING	-21	05NOV2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	011	1	V1 (WEEK 0)	1	26NOV2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V3 (WEEK 12)	85	18FEB2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V4 (WEEK 24)	162	06MAY2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	011	1	V4 (WEEK 24)	162	06MAY2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	253	05AUG2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	366	26NOV2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	397	27DEC2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	011	1	V7 (WEEK 56)	397	27DEC2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	013	4	SCREENING	-30	17AUG2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
					1 16SEP2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	013	4	V1 (WEEK 0)	1	16SEP2009	CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	09DEC2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	170	04MAR2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	247	20MAY2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	013	4	V5 (WEEK 36)	247	20MAY2010	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		4	V6 (WEEK 52)	366	16SEP2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
		4	V7 (WEEK 56)	400	20OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
	016	4	SCREENING	-28	01FEB2010	CRANIAL NERVES	NORMAL	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	016	4	SCREENING	-28	01FEB2010	MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	01MAR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	80	19MAY2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	016	4	V3 (WEEK 12)	80	19MAY2010	SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	162	09AUG2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	253	08NOV2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	365	28FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	016	4	V6 (WEEK 52)	365	28FEB2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		V7 (WEEK 56)	403	07APR2011		CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	018	5	SCREENING	-20	03NOV2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	018	5	V1 (WEEK 0)	1	23NOV2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V3 (WEEK 12)	86	16FEB2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V4 (WEEK 24)	170	11MAY2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	018	5	V4 (WEEK 24)	170	11MAY2010	REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	247	27JUL2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	366	23NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	387	14DEC2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	018	5	V7 (WEEK 56)	387	14DEC2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	020	5	SCREENING	-26	27JAN2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
		1	V1 (WEEK 0)	22FEB2010	REFLEXES LE	NORMAL		
					SENSATION LE	NORMAL		
					CEREBELLAR FUNCTION LE	NORMAL		
					CRANIAL NERVES	UNCHANGED		
					MUSCLE STRENGTH UE	UNCHANGED		
					REFLEXES UE	UNCHANGED		
					SENSATION UE	UNCHANGED		
					CEREBELLAR FUNCTION UE	UNCHANGED		
					MUSCLE STRENGTH LE	UNCHANGED		
					REFLEXES LE	UNCHANGED		
					SENSATION LE	UNCHANGED		

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	020	5	V1 (WEEK 0)	1	22FEB2010	CEREBELLAR FUNCTION LE	UNCHANGED	
	024	4	SCREENING	-31	16JUL2010	CRANIAL NERVES	ABNORMAL	HYPAKUSIS ON BOTH SIDES
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	16AUG2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	87	10NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	024	4	V3 (WEEK 12)	87	10NOV2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	171	02FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	246	18APR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	358	08AUG2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	024	4	V6 (WEEK 52)	358	08AUG2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	393	12SEP2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
	028	20	SCREENING	-8	18NOV2010	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	028	20	SCREENING	-8	18NOV2010	REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	26NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	89	22FEB2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	180	24MAY2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	028	20	V4 (WEEK 24)	180	24MAY2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	273	25AUG2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	364	24NOV2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	028	20	V7 (WEEK 56)	390	20DEC2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	029	8	SCREENING	-3	26JAN2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	29JAN2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	029	8	V1 (WEEK 0)	1	29JAN2010	MUSCLE STRENGTH LE	UNCHANGED	
			V3 (WEEK 12)	82	20APR2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	158	05JUL2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	245	30SEP2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	029	8	V5 (WEEK 36)	245	30SEP2010	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V6 (WEEK 52)	369	01FEB2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	391	23FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	029	8	V7 (WEEK 56)	391	23FEB2011	CEREBELLAR FUNCTION LE	UNCHANGED	
	031	8	SCREENING	-14	06MAY2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	20MAY2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	90	17AUG2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	031	8	V3 (WEEK 12)	90	17AUG2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	174	09NOV2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	251	25JAN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	363	17MAY2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	031	8	V6 (WEEK 52)	363	17MAY2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	391	14JUN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
	034	9	SCREENING	-22	24FEB2010	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	034	9	SCREENING	-22	24FEB2010	REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	18MAR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	83	08JUN2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	175	08SEP2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	034	9	V4 (WEEK 24)	175	08SEP2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	258	30NOV2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	363	15MAR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	034	9	V7 (WEEK 56)	399	20APR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	041	12	SCREENING	-16	23SEP2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	09OCT2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	041	12	V1 (WEEK 0)	1	09OCT2009	MUSCLE STRENGTH LE	UNCHANGED	
			V3 (WEEK 12)	89	05JAN2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	167	24MAR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	251	16JUN2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	041	12	V5 (WEEK 36)	251	16JUN2010	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	363	06OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	392	04NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	041	12	V7 (WEEK 56)	392	04NOV2010	CEREBELLAR FUNCTION LE	UNCHANGED	
	044	12	SCREENING	-28	04NOV2009	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	02DEC2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	24FEB2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	044	12	V3 (WEEK 12)	85	24FEB2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	176	26MAY2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	260	18AUG2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	365	01DEC2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	044	12	V6 (WEEK 52)	365	01DEC2010	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		11	V7 (WEEK 56)	400	05JAN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
	045	11	SCREENING	-14	07DEC2009	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
045	11	SCREENING	-14	07DEC2009	SENSATION UE	NORMAL		
					CEREBELLAR FUNCTION UE	NORMAL		
					MUSCLE STRENGTH LE	NORMAL		
					CRANIAL NERVES	NORMAL		
					MUSCLE STRENGTH UE	NORMAL		
					REFLEXES UE	NORMAL		

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	045	11	SCREENING	-14	07DEC2009	REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	21DEC2009	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	85	15MAR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	169	07JUN2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	045	11	V4 (WEEK 24)	169	07JUN2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V5 (WEEK 36)	260	06SEP2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	360	15DEC2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	045	11	V7 (WEEK 56)	393	17JAN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	047	11	SCREENING	-21	12JUL2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	02AUG2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	047	11	V1 (WEEK 0)	1	02AUG2010	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	80	20OCT2010	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	162	10JAN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	254	12APR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	047	11	V5 (WEEK 36)	254	12APR2011	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V6 (WEEK 52)	360	27JUL2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	393	29AUG2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	047	11	V7 (WEEK 56)	393	29AUG2011	CEREBELLAR FUNCTION LE	UNCHANGED	
	049	21	SCREENING	-51	06SEP2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	
			V1 (WEEK 0)	1	27OCT2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	84	18JAN2011	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	049	21	V3 (WEEK 12)	84	18JAN2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V4 (WEEK 24)	168	12APR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V5 (WEEK 36)	252	05JUL2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	051	21	SCREENING	-52	06SEP2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	28OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	97	01FEB2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	051	21	V3 (WEEK 12)	97	01FEB2011	REFLEXES LE	UNCHANGED	
			V4 (WEEK 24)	167	12APR2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	251	05JUL2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	363	25OCT2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	051	21	V6 (WEEK 52)	363	25OCT2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	391	22NOV2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
	056	5	SCREENING	-21	31MAR2010	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	056	5	SCREENING V1 (WEEK 0)	-21	31MAR2010	CEREBELLAR FUNCTION LE	NORMAL	
				1	21APR2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V3 (WEEK 12)			SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	168	05OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	056	5	V4 (WEEK 24)	168	05OCT2010	MUSCLE STRENGTH LE	UNCHANGED	
			V5 (WEEK 36)	259	04JAN2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	364	19APR2011	CRANIAL NERVES	UNCHANGED	
			V7 (WEEK 56)	393	18MAY2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	056	5	V7 (WEEK 56)	393	18MAY2011	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	058	1	SCREENING	-21	06DEC2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
		1	V1 (WEEK 0)	1	27DEC2010	REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	058	1	V1 (WEEK 0)	1	27DEC2010	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	93	29MAR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	166	10JUN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	260	12SEP2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	058	1	V5 (WEEK 36)	260	12SEP2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	345	06DEC2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	380	10JAN2012	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	059	1	SCREENING	-2	27DEC2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	29DEC2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	93	31MAR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	059	1	V3 (WEEK 12)	93	31MAR2011	REFLEXES LE	UNCHANGED	
			V4 (WEEK 24)	161	07JUN2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	254	08SEP2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	345	08DEC2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding					
Placebo	059	1	V6 (WEEK 52)	345	08DEC2011	SENSATION UE	UNCHANGED						
						CEREBELLAR FUNCTION UE	UNCHANGED						
						MUSCLE STRENGTH LE	UNCHANGED						
						REFLEXES LE	UNCHANGED						
						SENSATION LE	UNCHANGED						
						CEREBELLAR FUNCTION LE	UNCHANGED						
			V7 (WEEK 56)	380	12JAN2012	CRANIAL NERVES	UNCHANGED						
						MUSCLE STRENGTH UE	UNCHANGED						
						REFLEXES UE	UNCHANGED						
						SENSATION UE	UNCHANGED						
						CEREBELLAR FUNCTION UE	UNCHANGED						
						MUSCLE STRENGTH LE	UNCHANGED						
						REFLEXES LE	UNCHANGED						
						SENSATION LE	UNCHANGED						
						CEREBELLAR FUNCTION LE	UNCHANGED						
						065	16	SCREENING	-20	10AUG2010	CRANIAL NERVES	NORMAL	
											MUSCLE STRENGTH UE	NORMAL	
											REFLEXES UE	NORMAL	
	SENSATION UE	NORMAL											
	CEREBELLAR FUNCTION UE	NORMAL											
	MUSCLE STRENGTH LE	NORMAL											
	REFLEXES LE	NORMAL											
	SENSATION LE	NORMAL											

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	065	16	SCREENING V1 (WEEK 0)	-20 1	10AUG2010 30AUG2010	CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V3 (WEEK 12)	85	22NOV2010	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	141	17JAN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	065	16	V4 (WEEK 24)	141	17JAN2011	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	068	16	SCREENING	-27	26OCT2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
		16	V1 (WEEK 0)	1	22NOV2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
		16	V3 (WEEK 12)	81	10FEB2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	068	16	V3 (WEEK 12)	81	10FEB2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V4 (WEEK 24)	163	03MAY2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V5 (WEEK 36)	262	10AUG2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	068	16	V5 (WEEK 36)	262	10AUG2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	372	28NOV2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
		23				MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	414	09JAN2012	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	069	23	SCREENING	-13	24NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	069	23	SCREENING	-13	24NOV2010	SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	07DEC2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	93	09MAR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	069	23	V4 (WEEK 24)	164	19MAY2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V5 (WEEK 36)	261	24AUG2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V6 (WEEK 52)	373	14DEC2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	069	23	V6 (WEEK 52)	373	14DEC2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
		V7 (WEEK 56)		401	11JAN2012	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
	072	18	SCREENING	-20	01DEC2010	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
			V1 (WEEK 0)	1	21DEC2010			

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	072	18	V1 (WEEK 0)	1	21DEC2010	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V3 (WEEK 12)	85	15MAR2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
			V4 (WEEK 24)	169	07JUN2011	MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	072	18	V4 (WEEK 24)	169	07JUN2011	CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	262	08SEP2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	360	15DEC2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	393	17JAN2012	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	072	18	V7 (WEEK 56)	393	17JAN2012	MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
	079	13	SCREENING	-18	19JUL2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	
			V1 (WEEK 0)	1	06AUG2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	96	09NOV2010	CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	079	13	V3 (WEEK 12)	96	09NOV2010	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V4 (WEEK 24)	175	27JAN2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V5 (WEEK 36)	249	11APR2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	079	13	V5 (WEEK 36)	249	11APR2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	320	21JUN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	348	19JUL2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	082	17	SCREENING	-8	06OCT2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	082	17	SCREENING	-8	06OCT2010	SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	14OCT2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	84	05JAN2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	082	17	V4 (WEEK 24)	175	06APR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V5 (WEEK 36)	252	22JUN2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V6 (WEEK 52)	364	12OCT2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	082	17	V6 (WEEK 52)	364	12OCT2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
		V7 (WEEK 56)				CEREBELLAR FUNCTION LE	UNCHANGED	
			407	24NOV2011	CRANIAL NERVES	UNCHANGED		
					MUSCLE STRENGTH UE	UNCHANGED		
					REFLEXES UE	UNCHANGED		
					SENSATION UE	UNCHANGED		
					CEREBELLAR FUNCTION UE	UNCHANGED		
	084	17	SCREENING	-9	08NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	
						SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
V1 (WEEK 0)	1	17NOV2010	CEREBELLAR FUNCTION LE	NORMAL				
			CRANIAL NERVES	UNCHANGED				
			MUSCLE STRENGTH UE	UNCHANGED				

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	084	17	V1 (WEEK 0)	1	17NOV2010	REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	84	08FEB2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V4 (WEEK 24)	175	10MAY2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	084	17	V4 (WEEK 24)	175	10MAY2011	CEREBELLAR FUNCTION LE	UNCHANGED	
			V5 (WEEK 36)	259	02AUG2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V6 (WEEK 52)	371	22NOV2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
			V7 (WEEK 56)	394	15DEC2011	CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	084	17	V7 (WEEK 56)	394	15DEC2011	MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
	086	21	SCREENING	-24	04OCT2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	
			V1 (WEEK 0)	1	28OCT2010	CRANIAL NERVES MUSCLE STRENGTH UE REFLEXES UE SENSATION UE CEREBELLAR FUNCTION UE MUSCLE STRENGTH LE REFLEXES LE SENSATION LE CEREBELLAR FUNCTION LE	UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED UNCHANGED	
			V3 (WEEK 12)	83	18JAN2011	CRANIAL NERVES	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	086	21	V3 (WEEK 12)	83	18JAN2011	MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
			V4 (WEEK 24)	167	12APR2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
			V5 (WEEK 36)	251	05JUL2011	CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	086	21	V5 (WEEK 36)	251	05JUL2011	SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V6 (WEEK 52)	363	25OCT2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	391	22NOV2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
	088	16	SCREENING	-9	30NOV2010	CRANIAL NERVES	NORMAL	
						MUSCLE STRENGTH UE	NORMAL	
						REFLEXES UE	NORMAL	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	088	16	SCREENING	-9	30NOV2010	SENSATION UE	NORMAL	
						CEREBELLAR FUNCTION UE	NORMAL	
						MUSCLE STRENGTH LE	NORMAL	
						REFLEXES LE	NORMAL	
						SENSATION LE	NORMAL	
						CEREBELLAR FUNCTION LE	NORMAL	
			V1 (WEEK 0)	1	09DEC2010	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V3 (WEEK 12)	83	01MAR2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	088	16	V4 (WEEK 24)	162	19MAY2011	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
			V5 (WEEK 36)	264	29AUG2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
			V6 (WEEK 52)	376	19DEC2011	SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
						CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	

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Listing 16.2.9.4: Neurological examination

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Date of visit	Organ/System	Status	Finding
Placebo	088	16	V6 (WEEK 52)	376	19DEC2011	REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	
			V7 (WEEK 56)	404	16JAN2012	CRANIAL NERVES	UNCHANGED	
						MUSCLE STRENGTH UE	UNCHANGED	
						REFLEXES UE	UNCHANGED	
						SENSATION UE	UNCHANGED	
						CEREBELLAR FUNCTION UE	UNCHANGED	
						MUSCLE STRENGTH LE	UNCHANGED	
						REFLEXES LE	UNCHANGED	
						SENSATION LE	UNCHANGED	
						CEREBELLAR FUNCTION LE	UNCHANGED	

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
ACI-91	002	1	V2 (WEEK 4)	28	20MAY2009	GOOD
			V3 (WEEK 12)	85	16JUL2009	VERY GOOD
			V4 (WEEK 24)	169	08OCT2009	VERY GOOD
			V5 (WEEK 36)	258	05JAN2010	GOOD
			V6 (WEEK 52)	365	22APR2010	GOOD
	004	1	V2 (WEEK 4)	28	12AUG2009	VERY GOOD
			V3 (WEEK 12)	92	15OCT2009	VERY GOOD
	006	2	V2 (WEEK 4)	29	26MAR2010	VERY GOOD
			V3 (WEEK 12)	85	21MAY2010	VERY GOOD
			V4 (WEEK 24)	169	13AUG2010	VERY GOOD
			V5 (WEEK 36)	252	04NOV2010	VERY GOOD
			V6 (WEEK 52)	364	24FEB2011	VERY GOOD
	010	1	V2 (WEEK 4)	31	20AUG2009	VERY GOOD
			V3 (WEEK 12)	85	13OCT2009	GOOD
	012	1	V2 (WEEK 4)	25	12AUG2010	VERY GOOD
			V3 (WEEK 12)	88	14OCT2010	VERY GOOD
			V4 (WEEK 24)	176	10JAN2011	VERY GOOD
			V5 (WEEK 36)	257	01APR2011	VERY GOOD
			V6 (WEEK 52)	361	14JUL2011	VERY GOOD
	014	4	V2 (WEEK 4)	32	03DEC2009	VERY GOOD
			V3 (WEEK 12)	85	25JAN2010	VERY GOOD
			V4 (WEEK 24)	172	22APR2010	VERY GOOD
			V5 (WEEK 36)	256	15JUL2010	VERY GOOD
			V6 (WEEK 52)	361	28OCT2010	VERY GOOD
	015	4	V2 (WEEK 4)	29	22MAR2010	GOOD

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
ACI-91	015	4	V3 (WEEK 12)	85	17MAY2010	VERY GOOD
			V4 (WEEK 24)	162	02AUG2010	VERY GOOD
			V5 (WEEK 36)	248	27OCT2010	VERY GOOD
			V6 (WEEK 52)	365	21FEB2011	VERY GOOD
	017	5	UNSCHEDULED	9	13AUG2009	MODERATE
			UNSCHEDULED	16	20AUG2009	GOOD
			V2 (WEEK 4)	29	02SEP2009	MODERATE
			V3 (WEEK 12)	85	28OCT2009	GOOD
			V4 (WEEK 24)	169	20JAN2010	GOOD
			V5 (WEEK 36)	252	13APR2010	GOOD
			V6 (WEEK 52)	364	03AUG2010	GOOD
	019	5	V2 (WEEK 4)	29	06JAN2010	VERY GOOD
			V3 (WEEK 12)	85	03MAR2010	VERY GOOD
			V4 (WEEK 24)	168	25MAY2010	MODERATE
			V5 (WEEK 36)	259	24AUG2010	MODERATE
			V6 (WEEK 52)	364	07DEC2010	MODERATE
	023	4	V2 (WEEK 4)	24	12AUG2010	GOOD
			V3 (WEEK 12)	86	13OCT2010	VERY GOOD
			V4 (WEEK 24)	177	12JAN2011	VERY GOOD
			V5 (WEEK 36)	245	21MAR2011	VERY GOOD
			V6 (WEEK 52)	364	18JUL2011	GOOD
	027	20	V2 (WEEK 4)	29	18NOV2010	VERY GOOD
			V3 (WEEK 12)	92	20JAN2011	GOOD
			V4 (WEEK 24)	174	12APR2011	VERY GOOD
			V5 (WEEK 36)	259	06JUL2011	VERY GOOD

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
ACI-91	027	20	V6 (WEEK 52)	370	25OCT2011	VERY GOOD
			V2 (WEEK 4)	28	21APR2010	POOR
			V3 (WEEK 12)	85	17JUN2010	MODERATE
			V4 (WEEK 24)	163	03SEP2010	GOOD
			V5 (WEEK 36)	253	02DEC2010	GOOD
			V6 (WEEK 52)	355	14MAR2011	VERY GOOD
	032	8	V2 (WEEK 4)	30	17DEC2010	VERY GOOD
			V3 (WEEK 12)	82	07FEB2011	VERY GOOD
	033	9	V2 (WEEK 4)	29	02DEC2009	VERY GOOD
			V3 (WEEK 12)	78	20JAN2010	GOOD
			V4 (WEEK 24)	169	21APR2010	VERY GOOD
			V5 (WEEK 36)	261	22JUL2010	VERY GOOD
			V6 (WEEK 52)	372	10NOV2010	VERY GOOD
	042	12	V2 (WEEK 4)	29	11FEB2010	GOOD
			V3 (WEEK 12)	126	19MAY2010	GOOD
			V4 (WEEK 24)	168	30JUN2010	GOOD
			V5 (WEEK 36)	252	22SEP2010	GOOD
			V6 (WEEK 52)	364	12JAN2011	GOOD
	043	12	V2 (WEEK 4)	29	16DEC2009	GOOD
			V3 (WEEK 12)	85	10FEB2010	GOOD
			V4 (WEEK 24)	176	12MAY2010	GOOD
			V6 (WEEK 52)	267	11AUG2010	GOOD
	046	11	V2 (WEEK 4)	29	08FEB2010	VERY GOOD
			V3 (WEEK 12)	87	07APR2010	VERY GOOD
			V4 (WEEK 24)	178	07JUL2010	VERY GOOD

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
ACI-91	046	11	V5 (WEEK 36)	255	22SEP2010	GOOD
			V6 (WEEK 52)	367	12JAN2011	VERY GOOD
	048	11	V2 (WEEK 4)	30	21DEC2010	VERY GOOD
			V3 (WEEK 12)	86	15FEB2011	VERY GOOD
			V4 (WEEK 24)	176	16MAY2011	VERY GOOD
			V5 (WEEK 36)	247	26JUL2011	VERY GOOD
			V6 (WEEK 52)	360	16NOV2011	GOOD
	050	21	V2 (WEEK 4)	27	22NOV2010	VERY GOOD
			V3 (WEEK 12)	83	17JAN2011	VERY GOOD
			V4 (WEEK 24)	167	11APR2011	VERY GOOD
			UNSCHEDULED	211	25MAY2011	VERY GOOD
			V5 (WEEK 36)	251	04JUL2011	VERY GOOD
			V6 (WEEK 52)	363	24OCT2011	VERY GOOD
			UNSCHEDULED	366	27OCT2011	VERY GOOD
	052	21	V2 (WEEK 4)	27	23NOV2010	VERY GOOD
			V3 (WEEK 12)	82	17JAN2011	VERY GOOD
			V4 (WEEK 24)	166	11APR2011	VERY GOOD
			V5 (WEEK 36)	250	04JUL2011	VERY GOOD
			V6 (WEEK 52)	362	24OCT2011	VERY GOOD
	055	5	UNSCHEDULED	2	30MAR2010	VERY POOR
	057	1	V2 (WEEK 4)	33	20SEP2010	VERY GOOD
			V3 (WEEK 12)	82	08NOV2010	VERY GOOD
			V4 (WEEK 24)	170	04FEB2011	VERY GOOD
	066	16	V2 (WEEK 4)	28	06OCT2010	MODERATE
			V3 (WEEK 12)	83	30NOV2010	MODERATE

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
ACI-91	067	16	V2 (WEEK 4)	29	16DEC2010	POOR
			V6 (WEEK 52)	69	25JAN2011	VERY POOR
	071	18	V2 (WEEK 4)	24	02DEC2010	GOOD
			V3 (WEEK 12)	87	03FEB2011	GOOD
			UNSCHEDULED	99	15FEB2011	GOOD
			UNSCHEDULED	155	12APR2011	GOOD
			V4 (WEEK 24)	177	04MAY2011	GOOD
			V5 (WEEK 36)	253	19JUL2011	GOOD
			V6 (WEEK 52)	374	17NOV2011	GOOD
	080	13	V2 (WEEK 4)	26	13DEC2010	GOOD
			UNSCHEDULED	42	29DEC2010	GOOD
			V3 (WEEK 12)	84	09FEB2011	VERY GOOD
	081	17	V2 (WEEK 4)	33	15NOV2010	VERY GOOD
			V3 (WEEK 12)	89	10JAN2011	GOOD
			V4 (WEEK 24)	175	06APR2011	GOOD
			V5 (WEEK 36)	250	20JUN2011	GOOD
			V6 (WEEK 52)	376	24OCT2011	GOOD
	083	17	V2 (WEEK 4)	29	08DEC2010	GOOD
			V3 (WEEK 12)	85	02FEB2011	GOOD
			V4 (WEEK 24)	168	26APR2011	MODERATE
			V5 (WEEK 36)	258	25JUL2011	GOOD
			V6 (WEEK 52)	365	09NOV2011	GOOD
	087	16	V2 (WEEK 4)	30	28DEC2010	VERY GOOD
			V3 (WEEK 12)	81	17FEB2011	VERY GOOD
			UNSCHEDULED	94	02MAR2011	GOOD

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
ACI-91	087	16	UNSCHEDULED	99	07MAR2011	GOOD
			V4 (WEEK 24)	169	16MAY2011	VERY GOOD
			V5 (WEEK 36)	255	10AUG2011	MODERATE
			V6 (WEEK 52)	365	28NOV2011	VERY GOOD
	089	5	V2 (WEEK 4)	29	14DEC2010	VERY GOOD
			V3 (WEEK 12)	84	07FEB2011	VERY GOOD
			V4 (WEEK 24)	168	02MAY2011	VERY GOOD
			V5 (WEEK 36)	252	25JUL2011	VERY GOOD
			V6 (WEEK 52)	364	14NOV2011	VERY GOOD
	093	17	V2 (WEEK 4)	35	05JAN2011	VERY GOOD
			V3 (WEEK 12)	86	25FEB2011	MODERATE
			V4 (WEEK 24)	173	23MAY2011	MODERATE
			V5 (WEEK 36)	258	16AUG2011	MODERATE
	097	12	V6 (WEEK 52)	370	06DEC2011	MODERATE
			V2 (WEEK 4)	28	14DEC2010	GOOD
			V3 (WEEK 12)	85	09FEB2011	GOOD
Placebo	001	1	V2 (WEEK 4)	29	07MAY2009	GOOD
			V3 (WEEK 12)	90	07JUL2009	VERY GOOD
			V4 (WEEK 24)	162	17SEP2009	VERY GOOD
			V5 (WEEK 36)	246	10DEC2009	GOOD
			V6 (WEEK 52)	365	08APR2010	VERY GOOD
	003	1	V2 (WEEK 4)	28	24JUN2009	VERY GOOD
			V3 (WEEK 12)	90	25AUG2009	VERY GOOD
			V4 (WEEK 24)	169	12NOV2009	GOOD
			V5 (WEEK 36)	253	04FEB2010	GOOD

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
Placebo	005	2	V2 (WEEK 4)	27	30JUN2009	VERY GOOD
			V3 (WEEK 12)	83	25AUG2009	VERY GOOD
			V4 (WEEK 24)	168	18NOV2009	VERY GOOD
			V5 (WEEK 36)	258	16FEB2010	VERY GOOD
			V6 (WEEK 52)	364	02JUN2010	VERY GOOD
	009	1	V2 (WEEK 4)	30	07OCT2009	VERY GOOD
			V3 (WEEK 12)	94	10DEC2009	VERY GOOD
			V4 (WEEK 24)	178	04MAR2010	VERY GOOD
			V5 (WEEK 36)	246	11MAY2010	VERY GOOD
			V6 (WEEK 52)	361	03SEP2010	GOOD
	011	1	V2 (WEEK 4)	35	30DEC2009	VERY GOOD
			V3 (WEEK 12)	85	18FEB2010	VERY GOOD
			V4 (WEEK 24)	162	06MAY2010	GOOD
			V5 (WEEK 36)	253	05AUG2010	VERY GOOD
			V6 (WEEK 52)	366	26NOV2010	VERY GOOD
	013	4	V2 (WEEK 4)	29	14OCT2009	VERY GOOD
			V3 (WEEK 12)	85	09DEC2009	VERY GOOD
			V4 (WEEK 24)	170	04MAR2010	VERY GOOD
			V5 (WEEK 36)	247	20MAY2010	VERY GOOD
			V6 (WEEK 52)	366	16SEP2010	VERY GOOD
	016	4	V2 (WEEK 4)	29	29MAR2010	VERY GOOD
			V3 (WEEK 12)	80	19MAY2010	GOOD
			V4 (WEEK 24)	162	09AUG2010	GOOD
			V5 (WEEK 36)	253	08NOV2010	VERY GOOD
			V6 (WEEK 52)	365	28FEB2011	GOOD

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
Placebo	018	5	V2 (WEEK 4)	29	21DEC2009	VERY GOOD
			V3 (WEEK 12)	86	16FEB2010	VERY GOOD
			V4 (WEEK 24)	170	11MAY2010	VERY GOOD
			V5 (WEEK 36)	247	27JUL2010	VERY GOOD
			V6 (WEEK 52)	366	23NOV2010	VERY GOOD
	024	4	V2 (WEEK 4)	31	15SEP2010	VERY GOOD
			V3 (WEEK 12)	87	10NOV2010	VERY GOOD
			V4 (WEEK 24)	171	02FEB2011	VERY GOOD
			V5 (WEEK 36)	246	18APR2011	VERY GOOD
			V6 (WEEK 52)	358	08AUG2011	VERY GOOD
	028	20	V2 (WEEK 4)	26	21DEC2010	VERY GOOD
			V3 (WEEK 12)	89	22FEB2011	VERY GOOD
			V4 (WEEK 24)	180	24MAY2011	VERY GOOD
			V5 (WEEK 36)	273	25AUG2011	VERY GOOD
			V6 (WEEK 52)	364	24NOV2011	VERY GOOD
	029	8	V2 (WEEK 4)	34	03MAR2010	GOOD
			V3 (WEEK 12)	82	20APR2010	GOOD
			V4 (WEEK 24)	158	05JUL2010	VERY GOOD
			V5 (WEEK 36)	245	30SEP2010	VERY GOOD
			V6 (WEEK 52)	369	01FEB2011	VERY GOOD
	031	8	V2 (WEEK 4)	27	15JUN2010	VERY GOOD
			V3 (WEEK 12)	90	17AUG2010	VERY GOOD
			V4 (WEEK 24)	174	09NOV2010	GOOD
			V5 (WEEK 36)	251	25JAN2011	VERY GOOD
			V6 (WEEK 52)	363	17MAY2011	VERY GOOD

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Placebo	034	9	V2 (WEEK 4)	27	13APR2010	VERY GOOD
			V3 (WEEK 12)	83	08JUN2010	VERY GOOD
			V4 (WEEK 24)	175	08SEP2010	VERY GOOD
			V5 (WEEK 36)	258	30NOV2010	VERY GOOD
			V6 (WEEK 52)	363	15MAR2011	VERY GOOD
	041	12	V2 (WEEK 4)	32	09NOV2009	GOOD
			V3 (WEEK 12)	89	05JAN2010	VERY GOOD
			V4 (WEEK 24)	167	24MAR2010	VERY GOOD
			V5 (WEEK 36)	251	16JUN2010	GOOD
			V6 (WEEK 52)	363	06OCT2010	VERY GOOD
	044	12	V2 (WEEK 4)	37	07JAN2010	VERY GOOD
			V3 (WEEK 12)	85	24FEB2010	VERY GOOD
			V4 (WEEK 24)	176	26MAY2010	VERY GOOD
			V5 (WEEK 36)	260	18AUG2010	VERY GOOD
			V6 (WEEK 52)	365	01DEC2010	GOOD
	045	11	V2 (WEEK 4)	29	18JAN2010	VERY GOOD
			V3 (WEEK 12)	85	15MAR2010	VERY GOOD
			V4 (WEEK 24)	169	07JUN2010	VERY GOOD
			V5 (WEEK 36)	260	06SEP2010	VERY GOOD
			V6 (WEEK 52)	360	15DEC2010	VERY GOOD
	047	11	V2 (WEEK 4)	29	30AUG2010	GOOD
			V3 (WEEK 12)	80	20OCT2010	VERY GOOD
			V4 (WEEK 24)	162	10JAN2011	VERY GOOD
			V5 (WEEK 36)	254	12APR2011	VERY GOOD
			V6 (WEEK 52)	360	27JUL2011	GOOD

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
Placebo	049	21	V2 (WEEK 4)	27	22NOV2010	VERY GOOD
			V3 (WEEK 12)	84	18JAN2011	VERY GOOD
			V4 (WEEK 24)	168	12APR2011	VERY GOOD
			UNSCHEDULED	213	27MAY2011	VERY GOOD
			V5 (WEEK 36)	252	05JUL2011	VERY GOOD
			UNSCHEDULED	258	11JUL2011	VERY GOOD
			UNSCHEDULED	267	20JUL2011	VERY GOOD
			UNSCHEDULED	274	27JUL2011	VERY GOOD
			UNSCHEDULED	286	08AUG2011	VERY GOOD
			UNSCHEDULED	302	24AUG2011	VERY GOOD
	051	21	V2 (WEEK 4)	27	23NOV2010	VERY GOOD
			V3 (WEEK 12)	97	01FEB2011	VERY GOOD
			V4 (WEEK 24)	167	12APR2011	VERY GOOD
			V5 (WEEK 36)	251	05JUL2011	VERY GOOD
			V6 (WEEK 52)	363	25OCT2011	VERY GOOD
	056	5	V2 (WEEK 4)	29	19MAY2010	VERY GOOD
			V3 (WEEK 12)	84	13JUL2010	VERY GOOD
			V4 (WEEK 24)	168	05OCT2010	VERY GOOD
			V5 (WEEK 36)	259	04JAN2011	VERY GOOD
			V6 (WEEK 52)	364	19APR2011	VERY GOOD
	058	1	V2 (WEEK 4)	26	21JAN2011	VERY GOOD
			V3 (WEEK 12)	93	29MAR2011	VERY GOOD
			V4 (WEEK 24)	166	10JUN2011	VERY GOOD
			V5 (WEEK 36)	260	12SEP2011	VERY GOOD
			V6 (WEEK 52)	345	06DEC2011	VERY GOOD

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
Placebo	059	1	V2 (WEEK 4)	24	21JAN2011	VERY GOOD
			V3 (WEEK 12)	93	31MAR2011	GOOD
			V4 (WEEK 24)	161	07JUN2011	GOOD
			V5 (WEEK 36)	254	08SEP2011	GOOD
			V6 (WEEK 52)	345	08DEC2011	GOOD
	065	16	V2 (WEEK 4)	29	27SEP2010	VERY GOOD
			V3 (WEEK 12)	85	22NOV2010	VERY GOOD
			V4 (WEEK 24)	141	17JAN2011	VERY GOOD
	068	16	V2 (WEEK 4)	29	20DEC2010	VERY GOOD
			V3 (WEEK 12)	81	10FEB2011	VERY GOOD
			V4 (WEEK 24)	163	03MAY2011	VERY GOOD
			V5 (WEEK 36)	262	10AUG2011	VERY GOOD
			V6 (WEEK 52)	372	28NOV2011	VERY GOOD
	069	23	V2 (WEEK 4)	37	12JAN2011	GOOD
			V3 (WEEK 12)	93	09MAR2011	GOOD
			V4 (WEEK 24)	164	19MAY2011	GOOD
			V5 (WEEK 36)	261	24AUG2011	GOOD
			V6 (WEEK 52)	373	14DEC2011	VERY GOOD
	072	18	V2 (WEEK 4)	31	20JAN2011	VERY GOOD
			V3 (WEEK 12)	85	15MAR2011	GOOD
			V4 (WEEK 24)	169	07JUN2011	GOOD
			V5 (WEEK 36)	262	08SEP2011	GOOD
			V6 (WEEK 52)	360	15DEC2011	GOOD
	079	13	V2 (WEEK 4)	34	08SEP2010	VERY GOOD
			V3 (WEEK 12)	96	09NOV2010	VERY GOOD

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Listing 16.2.9.5: Tolerability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Tolerability assess- ment by investigator
Placebo	079	13	V4 (WEEK 24)	175	27JAN2011	VERY GOOD
			V5 (WEEK 36)	249	11APR2011	VERY GOOD
			V6 (WEEK 52)	320	21JUN2011	VERY GOOD
	082	17	V2 (WEEK 4)	35	17NOV2010	GOOD
			V3 (WEEK 12)	84	05JAN2011	GOOD
			V4 (WEEK 24)	175	06APR2011	VERY GOOD
			V5 (WEEK 36)	252	22JUN2011	GOOD
			V6 (WEEK 52)	364	12OCT2011	GOOD
	084	17	V2 (WEEK 4)	29	15DEC2010	GOOD
			V3 (WEEK 12)	84	08FEB2011	GOOD
			V4 (WEEK 24)	175	10MAY2011	GOOD
			V5 (WEEK 36)	259	02AUG2011	GOOD
			V6 (WEEK 52)	371	22NOV2011	GOOD
	086	21	V2 (WEEK 4)	27	23NOV2010	VERY GOOD
			V3 (WEEK 12)	83	18JAN2011	VERY GOOD
			V4 (WEEK 24)	167	12APR2011	VERY GOOD
			V5 (WEEK 36)	251	05JUL2011	VERY GOOD
			V6 (WEEK 52)	363	25OCT2011	VERY GOOD
	088	16	V2 (WEEK 4)	27	04JAN2011	VERY GOOD
			V3 (WEEK 12)	83	01MAR2011	VERY GOOD
			V4 (WEEK 24)	162	19MAY2011	GOOD
			V5 (WEEK 36)	264	29AUG2011	VERY GOOD
			V6 (WEEK 52)	376	19DEC2011	VERY GOOD

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	002	1	SCREENING	-7	16APR2009	YES	YES	YES				
			V1 (WEEK 0)	1	23APR2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	28	20MAY2009						YES	
			V3 (WEEK 12)	85	16JUL2009		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	169	08OCT2009	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	258	05JAN2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	365	22APR2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	20MAY2010		YES	YES			YES	
	004	1	SCREENING	-29	17JUN2009	YES	YES	YES				
			V1 (WEEK 0)	1	16JUL2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	28	12AUG2009						YES	
			V3 (WEEK 12)	92	15OCT2009		NO	NO	NO	NO	NO	PATIENT REFUSED
	006	2	SCREENING	-32	25JAN2010	YES	YES	YES				
			V1 (WEEK 0)	1	26FEB2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	26MAR2010						YES	
			V3 (WEEK 12)	85	21MAY2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	169	13AUG2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	252	04NOV2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	364	24FEB2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	390	22MAR2011		YES	YES			YES	
	010	1	SCREENING	-26	25JUN2009	YES	YES	YES				

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	010	1	V1 (WEEK 0)	1	21JUL2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	31	20AUG2009						YES	
			V3 (WEEK 12)	85	13OCT2009		YES	YES	YES	YES	YES	
	012	1	SCREENING	-32	17JUN2010	YES	YES	YES				
			V1 (WEEK 0)	1	19JUL2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	25	12AUG2010						YES	
			V3 (WEEK 12)	88	14OCT2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	176	10JAN2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	257	01APR2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	361	14JUL2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	396	18AUG2011		YES	YES			YES	
	014	4	SCREENING	-26	07OCT2009	YES	YES	YES				
			V1 (WEEK 0)	1	02NOV2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	32	03DEC2009						YES	
			V3 (WEEK 12)	85	25JAN2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	172	22APR2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	256	15JUL2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	361	28OCT2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	396	02DEC2010		YES	YES			YES	
	015	4	SCREENING	-32	21JAN2010	YES	YES	YES				
			V1 (WEEK 0)	1	22FEB2010	YES	YES	YES	YES	YES	YES	

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	015	4	V2 (WEEK 4)	29	22MAR2010							YES
			V3 (WEEK 12)	85	17MAY2010		YES	YES	YES	YES		YES
			V4 (WEEK 24)	162	02AUG2010	YES	YES	YES	YES	YES		YES
			V5 (WEEK 36)	248	27OCT2010		YES	YES	YES	YES		YES
			V6 (WEEK 52)	365	21FEB2011	YES	YES	YES	YES	YES		YES
			V7 (WEEK 56)	394	22MAR2011		YES	YES				YES
	017	5	SCREENING	-22	14JUL2009	YES	YES	YES				
			V1 (WEEK 0)	1	05AUG2009	YES	YES	YES	YES	YES		YES
			V2 (WEEK 4)	29	02SEP2009							YES
			V3 (WEEK 12)	85	28OCT2009		YES	YES	YES	YES		YES
			V4 (WEEK 24)	169	20JAN2010	YES	YES	YES	YES	YES		YES
			V5 (WEEK 36)	252	13APR2010		YES	YES	YES	YES		YES
			V6 (WEEK 52)	364	03AUG2010	YES	YES	YES	YES	YES		YES
			V7 (WEEK 56)	392	31AUG2010		YES	YES				YES
	019	5	SCREENING	-21	18NOV2009	YES	YES	YES				
			V1 (WEEK 0)	1	09DEC2009	YES	YES	YES	YES	YES		YES
			V2 (WEEK 4)	29	06JAN2010							YES
			V3 (WEEK 12)	85	03MAR2010		YES	YES	YES	YES		YES
			V4 (WEEK 24)	168	25MAY2010	YES	YES	YES	YES	YES		YES
			V5 (WEEK 36)	259	24AUG2010		YES	YES	YES	YES		YES
			V6 (WEEK 52)	364	07DEC2010	YES	YES	YES	YES	YES		YES
			V7 (WEEK 56)	399	11JAN2011		YES	YES				YES

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	023	4	SCREENING	-19	01JUL2010	YES	YES	YES				
			V1 (WEEK 0)	1	20JUL2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	24	12AUG2010						YES	
			V3 (WEEK 12)	86	13OCT2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	177	12JAN2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	245	21MAR2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	364	18JUL2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	388	11AUG2011		YES	YES			YES	
	027	20	SCREENING	-21	30SEP2010	YES	YES	YES				
			V1 (WEEK 0)	1	21OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	18NOV2010						YES	
			V3 (WEEK 12)	92	20JAN2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	174	12APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	259	06JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	370	25OCT2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	407	01DEC2011		YES	YES			YES	
	030	8	SCREENING	-7	18MAR2010	YES	YES	YES				
			V1 (WEEK 0)	1	25MAR2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	28	21APR2010						YES	
			V3 (WEEK 12)	85	17JUN2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	163	03SEP2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	253	02DEC2010		YES	YES	YES	YES	YES	

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	030	8	V6 (WEEK 52)	355	14MAR2011	YES	YES	YES	YES	YES	YES	NTB/ CDR WAS INTERRUPTED DUE TO SUSPECTED EPILEPTIC SEIZURE TMT NOT DONE
			V7 (WEEK 56)	383	11APR2011		YES	YES			YES	
	032	8	SCREENING	-10	08NOV2010	YES	YES	YES				PATIENT NOT COMPLIANT
			V1 (WEEK 0)	1	18NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	30	17DEC2010						YES	
			V3 (WEEK 12)	82	07FEB2011		NO	NO	YES	YES	YES	
	033	9	SCREENING	-7	28OCT2009	YES	YES	YES				
			V1 (WEEK 0)	1	04NOV2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	02DEC2009						YES	
			V3 (WEEK 12)	78	20JAN2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	169	21APR2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	261	22JUL2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	372	10NOV2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	398	06DEC2010		YES	YES			YES	
	042	12	SCREENING	-29	16DEC2009	YES	YES	YES				
			V1 (WEEK 0)	1	14JAN2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	11FEB2010						YES	
			V3 (WEEK 12)	126	19MAY2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	168	30JUN2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	252	22SEP2010		YES	YES	YES	YES	YES	

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	042	12	V6 (WEEK 52)	364	12JAN2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	391	08FEB2011		YES	YES			YES	
	043	12	SCREENING	-28	21OCT2009	YES	YES	YES				
			V1 (WEEK 0)	1	18NOV2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	16DEC2009						YES	
			V3 (WEEK 12)	85	10FEB2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	176	12MAY2010	YES	YES	YES	YES	YES	YES	
			V6 (WEEK 52)	267	11AUG2010	NO	NO	NO	YES	YES	YES	NO COOPERATION BY PATIENT BECAUSE OF BAD GENERAL CONDITION
	046	11	SCREENING	-28	14DEC2009	YES	YES	YES				
			V1 (WEEK 0)	1	11JAN2010	YES	NO	YES	YES	YES	YES	PATIENT WAS EXHAUSTED AND COULD NOT GO ON
			V2 (WEEK 4)	29	08FEB2010						YES	
			V3 (WEEK 12)	87	07APR2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	178	07JUL2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	255	22SEP2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	367	12JAN2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	07FEB2011		YES	YES			YES	
	048	11	SCREENING	-5	17NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	22NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	30	21DEC2010						YES	

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	048	11	V3 (WEEK 12)	86	15FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	176	16MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	247	26JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	360	16NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	395	21DEC2011		YES	YES			YES	
	050	21	SCREENING	-51	06SEP2010	YES	YES	YES				
			V1 (WEEK 0)	1	27OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	27	22NOV2010						YES	
			V3 (WEEK 12)	83	17JAN2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	167	11APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	251	04JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	363	24OCT2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	391	21NOV2011		YES	YES			YES	
	052	21	SCREENING	-52	06SEP2010	YES	YES	YES				
			V1 (WEEK 0)	1	28OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	27	23NOV2010						YES	
			V3 (WEEK 12)	82	17JAN2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	166	11APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	250	04JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	362	24OCT2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	390	21NOV2011		YES	YES			YES	

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Listing 16.2.9.6: Questionnaires and tests

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						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	055	5	SCREENING	-21	08MAR2010	YES	YES	YES				
			V1 (WEEK 0)	1	29MAR2010	YES	YES	YES	YES	YES	YES	
			V6 (WEEK 52)	30	27APR2010	YES	YES	YES	YES	YES	YES	
	057	1	SCREENING	-21	29JUL2010	YES	YES	YES				
			V1 (WEEK 0)	1	19AUG2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	33	20SEP2010						YES	
			V3 (WEEK 12)	82	08NOV2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	170	04FEB2011	YES	YES	YES	YES	YES	YES	
	066	16	SCREENING	-31	09AUG2010	YES	YES	YES				
			V1 (WEEK 0)	1	09SEP2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	28	06OCT2010						YES	
			V3 (WEEK 12)	83	30NOV2010		YES	YES	YES	YES	YES	
	067	16	SCREENING	-16	02NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	18NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	16DEC2010						YES	
			V6 (WEEK 52)	69	25JAN2011	NO	NO	NO	NO	YES	YES	PATIENT DID NOT WANT TO PERFORM TESTS.
			V7 (WEEK 56)	111	08MAR2011		NO	NO			NO	PATIENT DOESNT LIKE TO PERFORM ANY TESTS.
	071	18	SCREENING	-20	20OCT2010	YES	YES	YES				

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						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	071	18	V1 (WEEK 0)	1	09NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	24	02DEC2010						YES	
			V3 (WEEK 12)	87	03FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	177	04MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	253	19JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	374	17NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	392	05DEC2011		YES	YES			YES	
	080	13	SCREENING	-10	08NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	18NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	26	13DEC2010						YES	
			V3 (WEEK 12)	84	09FEB2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	196	01JUN2011	YES	NO	NO	NO	NO	NO	PAT. IS OVERSTRAINED WITH INTENSIVE TESTING DUE TO PSYCHOSIS
	081	17	SCREENING	-10	04OCT2010	YES	YES	YES				
			V1 (WEEK 0)	1	14OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	33	15NOV2010						YES	
			V3 (WEEK 12)	89	10JAN2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	175	06APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	250	20JUN2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	376	24OCT2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	405	22NOV2011		YES	YES			YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	083	17	SCREENING	-15	26OCT2010	YES	YES	YES				
			V1 (WEEK 0)	1	10NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	08DEC2010						YES	
			V3 (WEEK 12)	85	02FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	168	26APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	258	25JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	365	09NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	392	06DEC2011		YES	YES			YES	
	087	16	SCREENING	-20	09NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	29NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	30	28DEC2010						YES	
			V3 (WEEK 12)	81	17FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	169	16MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	255	10AUG2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	365	28NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	395	28DEC2011		YES	YES			YES	
	089	5	SCREENING	-28	19OCT2010	YES	YES	YES				
			V1 (WEEK 0)	1	16NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	14DEC2010						YES	
			V3 (WEEK 12)	84	07FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	168	02MAY2011	YES	NO	YES	YES	YES	YES	PATIENT WAS NOT ABLE TO PERFORM NTB AND ALSO PARTS OF ADAS-COX

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
ACI-91	089	5	V5 (WEEK 36)	252	25JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	364	14NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	394	14DEC2011		YES	YES			YES	
	093	17	SCREENING	-3	29NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	02DEC2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	35	05JAN2011						YES	
			V3 (WEEK 12)	86	25FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	173	23MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	258	16AUG2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	370	06DEC2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	392	28DEC2011		YES	YES			YES	
	097	12	SCREENING	-21	27OCT2010	YES	YES	YES				
			V1 (WEEK 0)	1	17NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	28	14DEC2010						YES	
			V3 (WEEK 12)	85	09FEB2011		YES	YES	YES	YES	YES	
Placebo	001	1	SCREENING	-7	02APR2009	YES	YES	YES				
			V1 (WEEK 0)	1	09APR2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	07MAY2009						YES	
			V3 (WEEK 12)	90	07JUL2009		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	162	17SEP2009	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	246	10DEC2009		YES	YES	YES	YES	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	001	1	V6 (WEEK 52)	365	08APR2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	06MAY2010		YES	YES			YES	
	003	1	SCREENING	-21	07MAY2009	YES	YES	YES				
			V1 (WEEK 0)	1	28MAY2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	28	24JUN2009						YES	
			V3 (WEEK 12)	90	25AUG2009		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	169	12NOV2009	YES	NO	YES	YES	YES	YES	PATIENT REFUSED
			V5 (WEEK 36)	253	04FEB2010		NO	NO	NO	NO	NO	--> COMMENT
	005	2	SCREENING	-16	19MAY2009	YES	YES	YES				
			V1 (WEEK 0)	1	04JUN2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	27	30JUN2009						YES	
			V3 (WEEK 12)	83	25AUG2009		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	168	18NOV2009	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	258	16FEB2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	364	02JUN2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	400	08JUL2010		YES	YES			YES	
	009	1	SCREENING	-33	06AUG2009	YES	YES	YES				
			V1 (WEEK 0)	1	08SEP2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	30	07OCT2009						YES	
			V3 (WEEK 12)	94	10DEC2009		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	178	04MAR2010	YES	YES	YES	YES	YES	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	009	1	V5 (WEEK 36)	246	11MAY2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	361	03SEP2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	389	01OCT2010		YES	YES			YES	
	011	1	SCREENING	-21	05NOV2009	YES	YES	YES				
			V1 (WEEK 0)	1	26NOV2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	35	30DEC2009						YES	
			V3 (WEEK 12)	85	18FEB2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	162	06MAY2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	253	05AUG2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	366	26NOV2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	397	27DEC2010		YES	YES			YES	
	013	4	SCREENING	-30	17AUG2009	YES	YES	YES				
			V1 (WEEK 0)	1	16SEP2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	14OCT2009						YES	
			V3 (WEEK 12)	85	09DEC2009		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	170	04MAR2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	247	20MAY2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	366	16SEP2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	400	20OCT2010		YES	YES			YES	
	016	4	SCREENING	-28	01FEB2010	YES	YES	YES				
			V1 (WEEK 0)	1	01MAR2010	YES	YES	YES	YES	YES	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	016	4	V2 (WEEK 4)	29	29MAR2010							YES
			V3 (WEEK 12)	80	19MAY2010		YES	YES	YES	YES		YES
			V4 (WEEK 24)	162	09AUG2010	YES	YES	YES	YES	YES		YES
			V5 (WEEK 36)	253	08NOV2010		YES	YES	YES	YES		YES
			V6 (WEEK 52)	365	28FEB2011	YES	YES	YES	YES	YES		YES
			V7 (WEEK 56)	403	07APR2011		YES	YES				YES
	018	5	SCREENING	-20	03NOV2009	YES	YES	YES				
			V1 (WEEK 0)	1	23NOV2009	YES	YES	YES	YES	YES		YES
			V2 (WEEK 4)	29	21DEC2009							YES
			V3 (WEEK 12)	86	16FEB2010		YES	YES	YES	YES		YES
			V4 (WEEK 24)	170	11MAY2010	YES	YES	YES	YES	YES		YES
			V5 (WEEK 36)	247	27JUL2010		YES	YES	YES	YES		YES
			V6 (WEEK 52)	366	23NOV2010	YES	YES	YES	YES	YES		YES
			V7 (WEEK 56)	387	14DEC2010		YES	YES				YES
	020	5	SCREENING	-26	27JAN2010	YES	YES	YES				
			V1 (WEEK 0)	1	22FEB2010	YES	YES	YES	YES	YES		YES
	024	4	SCREENING	-31	16JUL2010	YES	YES	YES				
			V1 (WEEK 0)	1	16AUG2010	YES	YES	YES	YES	YES		YES
			V2 (WEEK 4)	31	15SEP2010							YES
			V3 (WEEK 12)	87	10NOV2010		YES	YES	YES	YES		YES
			V4 (WEEK 24)	171	02FEB2011	YES	YES	YES	YES	YES		YES

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	024	4	V5 (WEEK 36)	246	18APR2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	358	08AUG2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	12SEP2011		YES	YES			YES	
	028	20	SCREENING	-8	18NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	26NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	26	21DEC2010						YES	
			V3 (WEEK 12)	89	22FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	180	24MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	273	25AUG2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	364	24NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	390	20DEC2011		YES	YES			YES	
	029	8	SCREENING	-3	26JAN2010	YES	YES	YES				
			V1 (WEEK 0)	1	29JAN2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	34	03MAR2010						YES	
			V3 (WEEK 12)	82	20APR2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	158	05JUL2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	245	30SEP2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	369	01FEB2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	391	23FEB2011		YES	YES			YES	
	031	8	SCREENING	-14	06MAY2010	YES	YES	YES				
			V1 (WEEK 0)	1	20MAY2010	YES	YES	YES	YES	YES	YES	

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	031	8	V2 (WEEK 4)	27	15JUN2010						YES	
			V3 (WEEK 12)	90	17AUG2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	174	09NOV2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	251	25JAN2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	363	17MAY2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	391	14JUN2011		YES	YES			YES	
	034	9	SCREENING	-22	24FEB2010	YES	NO	YES				PATIENT REFUSED NTB.
			V1 (WEEK 0)	1	18MAR2010	YES	NO	YES	YES	YES	YES	PATIENT REFUSED NTB.
			V2 (WEEK 4)	27	13APR2010						YES	
			V3 (WEEK 12)	83	08JUN2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	175	08SEP2010	YES	NO	YES	YES	YES	YES	PATIENT REFUSED NTB.
			V5 (WEEK 36)	258	30NOV2010		NO	YES	YES	YES	YES	PATIENT REFUSED NTB.
			V6 (WEEK 52)	363	15MAR2011	YES	NO	YES	YES	YES	YES	PATIENT REFUSED NTB.
			V7 (WEEK 56)	399	20APR2011		NO	YES			YES	PATIENT REFUSED NTB.
	041	12	SCREENING	-16	23SEP2009	YES	YES	YES				
			V1 (WEEK 0)	1	09OCT2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	32	09NOV2009						YES	
			V3 (WEEK 12)	89	05JAN2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	167	24MAR2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	251	16JUN2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	363	06OCT2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	392	04NOV2010		YES	YES			YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	044	12	SCREENING	-28	04NOV2009	YES	YES	YES				
			V1 (WEEK 0)	1	02DEC2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	37	07JAN2010						YES	
			V3 (WEEK 12)	85	24FEB2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	176	26MAY2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	260	18AUG2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	365	01DEC2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	400	05JAN2011		YES	YES			YES	
	045	11	SCREENING	-14	07DEC2009	YES	YES	YES				
			V1 (WEEK 0)	1	21DEC2009	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	18JAN2010						YES	
			V3 (WEEK 12)	85	15MAR2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	169	07JUN2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	260	06SEP2010		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	360	15DEC2010	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	17JAN2011		YES	YES			YES	
	047	11	SCREENING	-21	12JUL2010	YES	YES	YES				
			V1 (WEEK 0)	1	02AUG2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	30AUG2010						YES	
			V3 (WEEK 12)	80	20OCT2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	162	10JAN2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	254	12APR2011		YES	YES	YES	YES	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	047	11	V6 (WEEK 52)	360	27JUL2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	29AUG2011		YES	YES			YES	
	049	21	SCREENING	-51	06SEP2010	YES	YES	YES				
			V1 (WEEK 0)	1	27OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	27	22NOV2010						YES	
			V3 (WEEK 12)	84	18JAN2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	168	12APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	252	05JUL2011		YES	YES	YES	YES	YES	
	051	21	SCREENING	-52	06SEP2010	YES	YES	YES				
			V1 (WEEK 0)	1	28OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	27	23NOV2010						YES	
			V3 (WEEK 12)	97	01FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	167	12APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	251	05JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	363	25OCT2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	391	22NOV2011		YES	YES			YES	
	056	5	SCREENING	-21	31MAR2010	YES	YES	YES				
			V1 (WEEK 0)	1	21APR2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	19MAY2010						YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	056	5	V3 (WEEK 12)	84	13JUL2010		NO	YES	YES	YES	YES	PATIENT NOT ABLE TO SIT LONGER THAN 30 MIN AFTER SURGERY (SPINAL CANAL STENOSIS IN LAST WEEK)
			V4 (WEEK 24)	168	05OCT2010	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	259	04JAN2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	364	19APR2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	18MAY2011		YES	YES			YES	
	058	1	SCREENING	-21	06DEC2010	YES	YES	YES				
			V1 (WEEK 0)	1	27DEC2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	26	21JAN2011						YES	
			V3 (WEEK 12)	93	29MAR2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	166	10JUN2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	260	12SEP2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	345	06DEC2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	380	10JAN2012		YES	YES			YES	
	059	1	SCREENING	-2	27DEC2010	YES	YES	YES				
			V1 (WEEK 0)	1	29DEC2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	24	21JAN2011						YES	
			V3 (WEEK 12)	93	31MAR2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	161	07JUN2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	254	08SEP2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	345	08DEC2011	YES	YES	YES	YES	YES	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	059	1	V7 (WEEK 56)	380	12JAN2012		YES	YES			YES	
	065	16	SCREENING	-20	10AUG2010	YES	YES	YES				
			V1 (WEEK 0)	1	30AUG2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	27SEP2010						YES	
			V3 (WEEK 12)	85	22NOV2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	141	17JAN2011	YES	YES	YES	YES	YES	YES	
	068	16	SCREENING	-27	26OCT2010	YES	YES	YES				
			V1 (WEEK 0)	1	22NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	20DEC2010						YES	
			V3 (WEEK 12)	81	10FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	163	03MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	262	10AUG2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	372	28NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	414	09JAN2012		YES	YES			YES	
	069	23	SCREENING	-13	24NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	07DEC2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	37	12JAN2011						YES	
			V3 (WEEK 12)	93	09MAR2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	164	19MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	261	24AUG2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	373	14DEC2011	YES	YES	YES	YES	YES	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	069	23	V7 (WEEK 56)	401	11JAN2012		YES	YES			YES	
	072	18	SCREENING	-20	01DEC2010	YES	YES	YES				
			V1 (WEEK 0)	1	21DEC2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	31	20JAN2011						YES	
			V3 (WEEK 12)	85	15MAR2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	169	07JUN2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	262	08SEP2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	360	15DEC2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	393	17JAN2012		YES	YES			YES	
	079	13	SCREENING	-18	19JUL2010	YES	YES	YES				
			V1 (WEEK 0)	1	06AUG2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	34	08SEP2010						YES	
			V3 (WEEK 12)	96	09NOV2010		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	175	27JAN2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	249	11APR2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	320	21JUN2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	348	19JUL2011		YES	YES			YES	
	082	17	SCREENING	-8	06OCT2010	YES	YES	YES				
			V1 (WEEK 0)	1	14OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	35	17NOV2010						YES	
			V3 (WEEK 12)	84	05JAN2011		YES	YES	YES	YES	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	082	17	V4 (WEEK 24)	175	06APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	252	22JUN2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	364	12OCT2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	407	24NOV2011		YES	YES			YES	
	084	17	SCREENING	-9	08NOV2010	YES	YES	YES				
			V1 (WEEK 0)	1	17NOV2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	29	15DEC2010						YES	
			V3 (WEEK 12)	84	08FEB2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	175	10MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	259	02AUG2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	371	22NOV2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	394	15DEC2011		YES	YES			YES	
	086	21	SCREENING	-24	04OCT2010	YES	YES	YES				
			V1 (WEEK 0)	1	28OCT2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	27	23NOV2010						YES	
			V3 (WEEK 12)	83	18JAN2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	167	12APR2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	251	05JUL2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	363	25OCT2011	YES	YES	YES	YES	YES	YES	
			V7 (WEEK 56)	391	22NOV2011		YES	YES			YES	
	088	16	SCREENING	-9	30NOV2010	YES	YES	YES				

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Listing 16.2.9.6: Questionnaires and tests

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	TEST PERFORMED						Reason for not done
						MMSE	NTB	ADAS	CDR	DAD	NPI	
Placebo	088	16	V1 (WEEK 0)	1	09DEC2010	YES	YES	YES	YES	YES	YES	
			V2 (WEEK 4)	27	04JAN2011						YES	
			V3 (WEEK 12)	83	01MAR2011		YES	YES	YES	YES	YES	
			V4 (WEEK 24)	162	19MAY2011	YES	YES	YES	YES	YES	YES	
			V5 (WEEK 36)	264	29AUG2011		YES	YES	YES	YES	YES	
			V6 (WEEK 52)	376	19DEC2011	NO	NO	NO	NO	YES	YES	DUE TO PATIENT RESTLESSNESS AND COGNITIVE CONDITION
			V7 (WEEK 56)	404	16JAN2012		NO	NO			YES	DUE TO PATIENT COGNITIVE STATUS NTB AND ADAS-CG NOT DONE.

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Reason	Number of tablets dispensed	Number of tablets returned	Reason
ACI-91	002	1	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	28	YES		140	16	
			V3 (WEEK 12)	85	YES		210	26	
			V4 (WEEK 24)	169	YES		210	42	
			V5 (WEEK 36)	258	YES		280	33	
			V6 (WEEK 52)	365				72	
			V7 (WEEK 56)	393					
	004	1	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	28	YES		140	15	
			V3 (WEEK 12)	92	NO	PATIENT AND WIFE REFUSED TO CONTINUE THIS STUDY			NA DRUGS AND BLISTERS DESTROYED FROM THE WIFE OF THE PATIENT
	006	2	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	29	YES		140	15	
			V3 (WEEK 12)	85	YES		210	29	
			V4 (WEEK 24)	169	YES		210	44	
			V5 (WEEK 36)	252	YES		280	44	

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	002	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY	YES	
			V7 (WEEK 56)			NO	THERE WAS NO DIARY IN V6, BECAUSE OF END OF THE STUDY
	004	1	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		NO	DESTROYED FROM THE WIFE OF THE PATIENT
			V3 (WEEK 12)	NO	PATIENT AND WIFE REFUSED TO CONTINUE THIS STUDY		
	006	2	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned	Reason
ACI-91	006	2	V6 (WEEK 52) V7 (WEEK 56)	364 390			64	
	010	1	V1 (WEEK 0) V2 (WEEK 4) V3 (WEEK 12)	1 31 85	YES YES YES	70 140 210	9 37	
	012	1	V1 (WEEK 0) V2 (WEEK 4) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52) V7 (WEEK 56)	1 25 88 176 257 361 396	YES YES YES YES YES 	70 140 210 210 280	63 20 136 71	NA PATIENT FORGOT BOX WITH TABLETS AT HOME
	014	4	V1 (WEEK 0) V2 (WEEK 4) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36)	1 32 85 172 256	YES YES YES YES YES	70 140 210 210 280	10 34 35 42	

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	006	2	V6 (WEEK 52)	NO	NO DIARY NECESSARY AT VISIT 6	YES	NO DIARY HANDED OUT, BECAUSE MEDICATION WAS TERMINATED
			V7 (WEEK 56)			NO	
	010	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
	012	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO		YES	
			V7 (WEEK 56)			NO	
	014	4	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
ACI-91	014	4	V6 (WEEK 52)	361			73
			V7 (WEEK 56)	396			
	015	4	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	13
			V3 (WEEK 12)	85	YES	210	28
			V4 (WEEK 24)	162	YES	210	56
			V5 (WEEK 36)	248	YES	280	38
			V6 (WEEK 52)	365			46
			V7 (WEEK 56)	394			
	017	5	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	15
			V3 (WEEK 12)	85	YES	210	27
			V4 (WEEK 24)	169	YES	210	47
			V5 (WEEK 36)	252	YES	280	43
			V6 (WEEK 52)	364			57
			V7 (WEEK 56)	392			
	019	5	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	11

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	014	4	V6 (WEEK 52)	NO	NO DIARY AVAILABLE FOR VISIT 6!	YES	
			V7 (WEEK 56)			NO	DIARY WAS RETURNED ON VISIT 6
	015	4	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE FOR VISIT 6	YES	
			V7 (WEEK 56)			NO	NO DIARY AVAILABLE ON VISIT 6 !
	017	5	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY	YES	
			V7 (WEEK 56)			NO	NO DIARY DISPENSED (END OF STUDY)
	019	5	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
ACI-91	019	5	V3 (WEEK 12)	85	YES	210	31
			V4 (WEEK 24)	168	YES	210	49
			V5 (WEEK 36)	259	YES	280	35
			V6 (WEEK 52)	364			72
			V7 (WEEK 56)	399			
	023	4	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	24	YES	140	22
			V3 (WEEK 12)	86	YES	210	17
			V4 (WEEK 24)	177	YES	210	28
			V5 (WEEK 36)	245	YES	280	74
			V6 (WEEK 52)	364			44
			V7 (WEEK 56)	388			
	027	20	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	13
			V3 (WEEK 12)	92	YES	210	21
			V4 (WEEK 24)	174	YES	240	45
			V5 (WEEK 36)	259	YES	280	37
			V6 (WEEK 52)	370			90
			V7 (WEEK 56)	407			

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	019	5	V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY	YES	
			V7 (WEEK 56)			NO	NO DIARY DISPENSED AT V6
	023	4	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE AT VISIT 6!	YES	
			V7 (WEEK 56)			NO	NO DIARY AVAILABLE
	027	20	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO BOOK AVAILABLE	NO	PATIENT CANT'T FIND THE DIARY
			V7 (WEEK 56)			NO	NOT DISPENSED AT VISIT 6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Reason	Number of tablets dispensed	Number of tablets returned
ACI-91	030	8	V1 (WEEK 0)	1	NO	DONEZEPIL INCREASED AFTER SCREENING. PDF WAS WRITTEN!	70	
			V2 (WEEK 4)	28	YES		140	15
			V3 (WEEK 12)	85	YES		210	22
			V4 (WEEK 24)	163	YES		210	60
			V5 (WEEK 36)	253	YES		280	32
			V6 (WEEK 52)	355				76
			V7 (WEEK 56)	383				
	032	8	V1 (WEEK 0)	1	YES		70	
			V2 (WEEK 4)	30	YES		140	9

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	030	8	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NA	YES	
			V7 (WEEK 56)			NO	NA
	032	8	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Reason	Number of tablets dispensed	Number of tablets returned	Reason
ACI-91	032	8	V3 (WEEK 12)	82	NO	PAT. EXCLUDED FROM STUDY BECAUSE PAT CAN NOT FULLFIL THE STUDY PROCEDURE.		35	
	033	9	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	29	YES		140	14	
			V3 (WEEK 12)	78	YES			0	NA NO NEW TABLETS AVAILABLE
			V4 (WEEK 24)	169	YES		210	38	
			V5 (WEEK 36)	261	YES		280	26	
			V6 (WEEK 52)	372				58	
			V7 (WEEK 56)	398					
	042	12	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	29	YES		140		MEDICATION WAS THROWN AWAY
			V3 (WEEK 12)	126	YES		210	29	
			V4 (WEEK 24)	168	YES		210	49	
			V5 (WEEK 36)	252	YES		280	70	

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed
ACI-91	032	8	V3 (WEEK 12)	NO	PAT. EXCLUDED FROM STUDY.	YES
	033	9	V1 (WEEK 0)	YES		
			V2 (WEEK 4)	YES		YES
			V3 (WEEK 12)	YES		YES
			V4 (WEEK 24)	YES		YES
			V5 (WEEK 36)	YES		YES
			V6 (WEEK 52)	NO		YES
			V7 (WEEK 56)			NO
	042	12	V1 (WEEK 0)	YES		
			V2 (WEEK 4)	YES		YES
			V3 (WEEK 12)	YES		YES
			V4 (WEEK 24)	YES		YES
			V5 (WEEK 36)	YES		YES

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned	Reason
ACI-91	042	12	V6 (WEEK 52)	364			70	
			V7 (WEEK 56)	391				
	043	12	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	29	YES	140	15	
			V3 (WEEK 12)	85	YES	210	28	
			V4 (WEEK 24)	176	YES	210	43	
			V6 (WEEK 52)	267			38	
	046	11	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	29	YES	140	14	
			V3 (WEEK 12)	87	YES	210	31	
			V4 (WEEK 24)	178	YES	210	28	
			V5 (WEEK 36)	255	YES	280	50	6 TABLETS LOST IN A BLISTER
			V6 (WEEK 52)	367			56	
			V7 (WEEK 56)	393				
	048	11	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	30	YES	140	8	
			V3 (WEEK 12)	86	YES	210	29	
			V4 (WEEK 24)	176	YES	210	31	
			V5 (WEEK 36)	247	YES	280	69	

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	042	12	V6 (WEEK 52)	NO	NO DIARY AT V6	YES	
			V7 (WEEK 56)			NO	NO DIARY AT VISIT V6
	043	12	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V6 (WEEK 52)	NO	STUDY TERMINATION	YES	
	046	11	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE	YES	
			V7 (WEEK 56)			NO	NO DIARY
	048	11	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned	Reason
ACI-91	048	11	V6 (WEEK 52)	360			56	
			V7 (WEEK 56)	395				
	050	21	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	27	YES	140		NA PATIENT/CAREGIVER FORGOT MEDICATION
			V3 (WEEK 12)	83	YES	210	43	
			V4 (WEEK 24)	167	YES	210	0	
			V5 (WEEK 36)	251	YES	280	0	
			V6 (WEEK 52)	363			92	
			V7 (WEEK 56)	391				
	052	21	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	27	YES	140		NA CAREGIVER FORGOT MEDICATION
			V3 (WEEK 12)	82	YES	210	0	
			V4 (WEEK 24)	166	YES	210	110	
			V5 (WEEK 36)	250	YES	280	50	
			V6 (WEEK 52)	362			72	
			V7 (WEEK 56)	390				
	055	5	V1 (WEEK 0)	1	YES	70		

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	048	11	V6 (WEEK 52)	NO	AT VISIT 6 NO PATIENT DIARY HAS TO BE DISPENSED	YES	
			V7 (WEEK 56)			NO	THERE WAS NO DIARY DISPLACED
	050	21	V1 (WEEK 0)	YES	NO DIARY AVAILABLE.	NO	PATIENT/CAREGIVER FORGOT DIARY
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO		YES	
			V7 (WEEK 56)			NO	N/A
	052	21	V1 (WEEK 0)	YES	NO PATIENT DIARY AVAILABLE.	YES	
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO		YES	
			V7 (WEEK 56)			NO	N/A
	055	5	V1 (WEEK 0)	YES			

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
ACI-91	055	5	V6 (WEEK 52)	30			69
	057	1	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	33	YES	140	5
			V3 (WEEK 12)	82	YES		44
			V4 (WEEK 24)	170	YES	210	80
	066	16	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	28	YES	140	25
			V3 (WEEK 12)	83	YES	210	31
	067	16	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	13
			V6 (WEEK 52)	69			133
			V7 (WEEK 56)	111			
	071	18	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	24	YES	140	25
			V3 (WEEK 12)	87	YES	210	14
			V4 (WEEK 24)	177	YES	210	30
			V5 (WEEK 36)	253	YES	280	58
			V6 (WEEK 52)	374			38

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	055	5	V6 (WEEK 52)	NO	EARLY TERMINATION	NO	
	057	1	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
	066	16	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
	067	16	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		YES	
			V6 (WEEK 52)	NO	EARLY TERMINATION	NO	EARLY TERMINATION
			V7 (WEEK 56)			NO	
	071	18	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned	Reason
ACI-91	071	18	V7 (WEEK 56)	392				
	080	13	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	26	YES	140	20	PATIENT AND CAREGIVER HAVE FORGOTTEN TO RETURN THE STUDY MEDICATION
			V3 (WEEK 12)	84	YES	210	26	
			V6 (WEEK 52)	196			164	
	081	17	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	33	YES	140	10	
			V3 (WEEK 12)	89	YES	210	29	
			V4 (WEEK 24)	175	YES	210	39	
			V5 (WEEK 36)	250	YES	280	58	
			V6 (WEEK 52)	376			28	
			V7 (WEEK 56)	405				
	083	17	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	29	YES	140	14	
			V3 (WEEK 12)	85	YES	210	9	
			V4 (WEEK 24)	168	YES	210	44	
			V5 (WEEK 36)	258	YES	280	19	

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	071	18	V7 (WEEK 56)			YES	
			V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
		13	V3 (WEEK 12)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY TREATMENT	YES	
	081	17	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	PAT. DIARY NOT AVAILABLE AT V6	YES	
			V7 (WEEK 56)			NO	NO DIARY DISPENSED AT V6
	083	17	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
ACI-91	083	17	V6 (WEEK 52)	365			88
			V7 (WEEK 56)	392			
	087	16	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	30	YES	140	13
			V3 (WEEK 12)	81	YES	210	38
			V4 (WEEK 24)	169	YES	210	36
			V5 (WEEK 36)	255	YES	280	40
			V6 (WEEK 52)	365			62
			V7 (WEEK 56)	395			
	089	5	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	16
			V3 (WEEK 12)	84	YES	210	29
			V4 (WEEK 24)	168	YES	210	42
			V5 (WEEK 36)	252	YES	280	42
			V6 (WEEK 52)	364			56
			V7 (WEEK 56)	394			
	093	17	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	35	YES	140	2
			V3 (WEEK 12)	86	YES	210	37

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	083	17	V6 (WEEK 52)	NO	NO DIARY	YES	
			V7 (WEEK 56)			NO	
	087	16	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	N.A.	YES	
			V7 (WEEK 56)			NO	NA
	089	5	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY TREATMENT	YES	
			V7 (WEEK 56)			YES	
	093	17	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Reason	Number of tablets dispensed	Number of tablets returned	Reason
ACI-91	093	17	V4 (WEEK 24)	173	YES		210	31	
			V5 (WEEK 36)	258	YES		280	37	
			V6 (WEEK 52)	370				56	
			V7 (WEEK 56)	392					
	097	12	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	28	YES		140	20	
			V3 (WEEK 12)	85	YES		210	27	
Placebo	001	1	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	29	YES		140	13	
			V3 (WEEK 12)	90	YES		210	18	
			V4 (WEEK 24)	162	YES	DRUGS TODAY 17/09/09 NOT AVAILABLE			NA DRUGS FOR VISIT 4 NOT AVAILABLE YET. ON 24.09.09 50 TABLETS RETURNED AND 210 TABLETS (V4) DISPENSED
			V5 (WEEK 36)	246	YES		280	56	
			V6 (WEEK 52)	365				42	
			V7 (WEEK 56)	393					
	003	1	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	28	YES		140	15	

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
ACI-91	093	17	V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY	YES	
			V7 (WEEK 56)			NO	NO DIARY
	097	12	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
	001	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY	YES	
			V7 (WEEK 56)			NO	
	003	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Reason	Number of tablets dispensed	Number of tablets returned	Reason
Placebo	003	1	V3 (WEEK 12)	90	YES		210	17	
			V4 (WEEK 24)	169	YES		210	52	
			V5 (WEEK 36)	253	NO	--> COMMENT		42	
	005	2	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	27	YES		140	4	
			V3 (WEEK 12)	83	YES		210	26	
			V4 (WEEK 24)	168	YES		210	46	
			V5 (WEEK 36)	258	YES		280		NA PATIENT DID NOT RETURN MEDICATION
			V6 (WEEK 52)	364				59	
			V7 (WEEK 56)	400					
	009	1	V1 (WEEK 0)	1	YES		70		
			V2 (WEEK 4)	30	YES		140	13	
			V3 (WEEK 12)	94	YES		210	12	
			V4 (WEEK 24)	178	YES		210	42	
			V5 (WEEK 36)	246	YES		280	74	
			V6 (WEEK 52)	361				50	
			V7 (WEEK 56)	389					

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	003	1	V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	NO	--> COMMENT	YES	
	005	2	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		NO	PATIENT DID NOT BRING DIARY
		V6 (WEEK 52) V7 (WEEK 56)		NO	THERE IS NO DIARY FOR THIS VISIT	YES	
						NO	NO EXISTING DIARY FOR FOLLOW-UP VISIT
	009	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY	YES	
			V7 (WEEK 56)			NO	END OF STUDY, NO DIARY IN V6

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
Placebo	011	1	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	35	YES	140	3
			V3 (WEEK 12)	85	YES	210	39
			V4 (WEEK 24)	162	YES	210	56
			V5 (WEEK 36)	253	YES	280	28
			V6 (WEEK 52)	366			54
			V7 (WEEK 56)	397			
	013	4	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	16
			V3 (WEEK 12)	85	YES	210	23
			V4 (WEEK 24)	170	YES	210	42
			V5 (WEEK 36)	247	YES	280	61
			V6 (WEEK 52)	366			45
			V7 (WEEK 56)	400			
	016	4	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	14
			V3 (WEEK 12)	80	YES	210	37
			V4 (WEEK 24)	162	YES	210	45
			V5 (WEEK 36)	253	YES	280	24
			V6 (WEEK 52)	365			52

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	011	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	ENDO OF STUDY	YES	
			V7 (WEEK 56)			NO	NO DIARY IN V6
	013	4	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO PATIENT DIARY AVAILABLE FOR V6!	YES	
			V7 (WEEK 56)			NO	NO DIARY AVAILABLE ON VISIT 6
	016	4	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE AFTER VISIT 6!	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
Placebo	016	4	V7 (WEEK 56)	403			
	018	5	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	5
			V3 (WEEK 12)	86	YES	210	34
			V4 (WEEK 24)	170	YES	210	36
			V5 (WEEK 36)	247	YES	280	56
			V6 (WEEK 52)	366			43
			V7 (WEEK 56)	387			
	020	5	V1 (WEEK 0)	1	YES	70	
	024	4	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	31	YES	140	9
			V3 (WEEK 12)	87	YES	210	28
			V4 (WEEK 24)	171	YES	210	38
			V5 (WEEK 36)	246	YES	280	58
			V6 (WEEK 52)	358			67
			V7 (WEEK 56)	393			
	028	20	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	26	YES	140	21

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	016	4	V7 (WEEK 56)			NO	NO DIARY WAS ISSUED AT VISIT 6
	018	5	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY	YES	
			V7 (WEEK 56)			NO	NO DIARY AT V6
	020	5	V1 (WEEK 0)	YES			
	024	4	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NOT AVAIABLE FOR VISIT 6	YES	
			V7 (WEEK 56)			NO	NO DIARY AVAILABLE AT VISIT 6!
	028	20	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Reason	Number of tablets dispensed	Number of tablets returned
Placebo	028	20	V3 (WEEK 12)	89	YES		210	19
			V4 (WEEK 24)	180	YES		210	40
			V5 (WEEK 36)	273	YES		280	26
			V6 (WEEK 52)	364				104
			V7 (WEEK 56)	390				
	029	8	V1 (WEEK 0)	1	YES		70	
			V2 (WEEK 4)	34	NO	DONEZEPIL INCREASED ON DAY OF SCREENING	140	4
			V3 (WEEK 12)	82	YES		210	45
			V4 (WEEK 24)	158	YES		210	60
			V5 (WEEK 36)	245	YES		280	36
			V6 (WEEK 52)	369				32
			V7 (WEEK 56)	391				
	031	8	V1 (WEEK 0)	1	YES		70	
			V2 (WEEK 4)	27	YES		140	18
			V3 (WEEK 12)	90	YES		210	14
			V4 (WEEK 24)	174	YES		210	43
			V5 (WEEK 36)	251	YES		280	57

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	028	20	V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NOT AVAILABLE	YES	
			V7 (WEEK 56)			NO	NOT DISPENSED
	029	8	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NA	YES	
			V7 (WEEK 56)			NO	NA
	031	8	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned	Reason
Placebo	031	8	V6 (WEEK 52) V7 (WEEK 56)	363 391			63	
	034	9	V1 (WEEK 0) V2 (WEEK 4) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52) V7 (WEEK 56)	1 27 83 175 258 363 399	YES YES YES YES YES	140 140 210 210 280	26 25 45 73	NA WAS FORGOTTEN, WILL BE DELIVERED NEXT VISIT
	041	12	V1 (WEEK 0) V2 (WEEK 4) V3 (WEEK 12) V4 (WEEK 24) V5 (WEEK 36) V6 (WEEK 52) V7 (WEEK 56)	1 32 89 167 251 363 392	YES YES YES YES YES	70 140 210 210 280	7 27 43 38 54	
	044	12	V1 (WEEK 0) V2 (WEEK 4)	1 37	YES YES	70 140	11	

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	031	8	V6 (WEEK 52)	NO	NA	YES	
			V7 (WEEK 56)			NO	NA
	034	9	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO		YES	
			V7 (WEEK 56)			NO	NO DIARY DISPENSED
	041	12	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE AT VISIT 6	YES	
			V7 (WEEK 56)			YES	
	044	12	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
Placebo	044	12	V3 (WEEK 12)	85	YES	210	69
			V4 (WEEK 24)	176	YES	210	109
			V5 (WEEK 36)	260	YES	280	150
			V6 (WEEK 52)	365			234
			V7 (WEEK 56)	400			
	045	11	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	15
			V3 (WEEK 12)	85	YES	210	37
			V4 (WEEK 24)	169	YES	210	53
			V5 (WEEK 36)	260	YES	280	34
			V6 (WEEK 52)	360			80
			V7 (WEEK 56)	393			
	047	11	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	14
			V3 (WEEK 12)	80	YES	210	38
			V4 (WEEK 24)	162	YES	210	46
			V5 (WEEK 36)	254	YES	280	26
			V6 (WEEK 52)	360			68

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	044	12	V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE ON VISIT 6	YES	
			V7 (WEEK 56)			NO	NO DIARY AT V6
	045	11	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARIES	YES	
			V7 (WEEK 56)			NO	NO DIARY IN VISIT 6
	047	11	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	AT VISIT 6 NO PATIENT DIARY HAS TO BE DISPENSED	YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
Placebo	047	11	V7 (WEEK 56)	393			
	049	21	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	27	YES	140	20
			V3 (WEEK 12)	84	YES	210	29
			V4 (WEEK 24)	168	YES	210	42
			V5 (WEEK 36)	252	YES	280	42
	051	21	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	27	YES	140	17
			V3 (WEEK 12)	97	YES	210	1
			V4 (WEEK 24)	167	YES	210	70
			V5 (WEEK 36)	251	YES	280	42
			V6 (WEEK 52)	363			56
			V7 (WEEK 56)	391			
	056	5	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	13
			V3 (WEEK 12)	84	YES	210	35
			V4 (WEEK 24)	168	YES	210	43

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	047	11	V7 (WEEK 56)			NO	AT VISIT 6 NO PATIENT DIARY WAS DISPENSED ACCORDING TO THE PROTOCOL
	049	21	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
	051	21	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO PATIENT DIARY AVAILABLE	YES	
			V7 (WEEK 56)			NO	N/A
	056	5	V1 (WEEK 0)	YES		YES	
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned	Reason
Placebo	056	5	V5 (WEEK 36)	259	YES	280	30	
			V6 (WEEK 52)	364			73	
			V7 (WEEK 56)	393				
	058	1	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	26	YES	140	20	
			V3 (WEEK 12)	93	YES	210	7	
			V4 (WEEK 24)	166	YES	210		
			V5 (WEEK 36)	260	YES	280	237	NA MEDICATION RETURNED AT V5
			V6 (WEEK 52)	345			121	
			V7 (WEEK 56)	380				
	059	1	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	24	YES	140	25	
			V3 (WEEK 12)	93	YES	210	5	
			V4 (WEEK 24)	161	YES	210	70	
			V5 (WEEK 36)	254	YES	280	30	
			V6 (WEEK 52)	345			104	
			V7 (WEEK 56)	380				
	065	16	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	29	YES	140	14	

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	056	5	V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY	YES	
			V7 (WEEK 56)			NO	NO DIARY DISPENDED AT V6
	058	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	13.12.2011 END OF MEDICATION	NO	CEREBROSPINAL FS 13.12.2011
			V7 (WEEK 56)			NO	NO MEDICATION - END 13.12.11
	059	1	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF MEDICATION	YES	
			V7 (WEEK 56)			NO	MEDICATION ENDS 7.12.11
	065	16	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	

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Placebo	065	16	V3 (WEEK 12)	85	YES	210	28	
			V4 (WEEK 24)	141	YES	210	98	
	068	16	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	29	YES	140	13	
			V3 (WEEK 12)	81	YES	210	55	
			V4 (WEEK 24)	163	YES	210	0	
			V5 (WEEK 36)	262	YES	280	108	
			V6 (WEEK 52)	372			0	PATIENT FORGOTT MEDICATION AT HOME
			V7 (WEEK 56)	414				
	069	23	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	37	YES	140	0	
			V3 (WEEK 12)	93	YES	210	27	
			V4 (WEEK 24)	164	YES	210	69	
			V5 (WEEK 36)	261	YES	280	16	
			V6 (WEEK 52)	373			55	
			V7 (WEEK 56)	401				
	072	18	V1 (WEEK 0)	1	YES	70		
			V2 (WEEK 4)	31	YES	140	12	

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	065	16	V3 (WEEK 12)	YES		NO	PATIENT FORGOT DIARY AT HOME
			V4 (WEEK 24)	YES		YES	
	068	16	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NA	NO	PATIENT FORGOT DIARY AT HOME
			V7 (WEEK 56)			YES	
	069	23	V1 (WEEK 0)	YES	N.A.		
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE	YES	
			V7 (WEEK 56)			NO	NOT AVAILABLE
	072	18	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
Placebo	072	18	V3 (WEEK 12)	85	YES	210	37
			V4 (WEEK 24)	169	YES	210	51
			V5 (WEEK 36)	262	YES	280	32
			V6 (WEEK 52)	360			135
			V7 (WEEK 56)	393			
	079	13	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	34	YES	140	15
			V3 (WEEK 12)	96	YES	210	16
			V4 (WEEK 24)	175	YES	210	58
			V5 (WEEK 36)	249	YES	280	64
			V6 (WEEK 52)	320			141
			V7 (WEEK 56)	348			
	082	17	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	35	YES	140	0
			V3 (WEEK 12)	84	YES	210	40
			V4 (WEEK 24)	175	YES	210	32
			V5 (WEEK 36)	252	YES	280	56
			V6 (WEEK 52)	364			74
			V7 (WEEK 56)	407			

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	072	18	V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	YES		YES	
			V7 (WEEK 56)			YES	
	079	13	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	END OF STUDY TREATMENT	YES	
			V7 (WEEK 56)			NO	NO DIARY WAS AVAILABLE IN CRF, SO NO DIARY WAS DISPENSED.
	082	17	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO		YES	
			V7 (WEEK 56)			NO	NO DIARY

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
Placebo	084	17	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	29	YES	140	17
			V3 (WEEK 12)	84	YES	210	30
			V4 (WEEK 24)	175	YES	210	26
			V5 (WEEK 36)	259	YES	280	40
			V6 (WEEK 52)	371			57
			V7 (WEEK 56)	394			
	086	21	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	27	YES	140	21
			V3 (WEEK 12)	83	YES	210	34
			V4 (WEEK 24)	167	YES	210	51
			V5 (WEEK 36)	251	YES	280	47
			V6 (WEEK 52)	363			66
			V7 (WEEK 56)	391			
	088	16	V1 (WEEK 0)	1	YES	70	
			V2 (WEEK 4)	27	YES	140	19
			V3 (WEEK 12)	83	YES	210	28
			V4 (WEEK 24)	162	YES	210	54
			V5 (WEEK 36)	264	YES	280	9
			V6 (WEEK 52)	376			56

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Reason	Diary re- turned and re- viewed	Reason
Placebo	084	17	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO DIARY AVAILABLE AT V6	YES	
			V7 (WEEK 56)			NO	NO DIARY
	086	21	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NO PATIENT DIARY AVAILABLE	YES	
			V7 (WEEK 56)			NO	N/A
	088	16	V1 (WEEK 0)	YES			
			V2 (WEEK 4)	YES		YES	
			V3 (WEEK 12)	YES		YES	
			V4 (WEEK 24)	YES		YES	
			V5 (WEEK 36)	YES		YES	
			V6 (WEEK 52)	NO	NA	YES	

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Actual day	Subject still eligible	Number of tablets dispensed	Number of tablets returned
Placebo	088	16	V7 (WEEK 56)	404			

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Listing 16.2.10.1: Drug accountability

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Treat- ment	Random No.	Site ID	Visit	Diary dis- pensed	Diary re- turned and re- viewed	Reason
Placebo	088	16	V7 (WEEK 56)		NO	NA

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	002	1	SCREENING	-7	16APR2009	YES	
			V1 (WEEK 0)	1	23APR2009	YES	YES
			V2 (WEEK 4)	28	20MAY2009	YES	YES
			V3 (WEEK 12)	85	16JUL2009	YES	YES
			V4 (WEEK 24)	169	08OCT2009	YES	YES
			V5 (WEEK 36)	258	05JAN2010	YES	YES
			V6 (WEEK 52)	365	22APR2010	YES	YES
			V7 (WEEK 56)	393	20MAY2010	YES	YES
	004	1	SCREENING	-29	17JUN2009	YES	
			V1 (WEEK 0)	1	16JUL2009	YES	YES
			V2 (WEEK 4)	28	12AUG2009	YES	YES
			V3 (WEEK 12)	92	15OCT2009	YES	YES
	006	2	SCREENING	-32	25JAN2010	YES	
			V1 (WEEK 0)	1	26FEB2010	YES	YES
			V2 (WEEK 4)	29	26MAR2010	YES	YES
			V3 (WEEK 12)	85	21MAY2010	YES	YES
			V4 (WEEK 24)	169	13AUG2010	YES	YES
			V5 (WEEK 36)	252	04NOV2010	YES	YES
			V6 (WEEK 52)	364	24FEB2011	YES	YES
			V7 (WEEK 56)	390	22MAR2011	YES	YES
	010	1	SCREENING	-26	25JUN2009	YES	

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	010	1	V1 (WEEK 0)	1	21JUL2009	YES	YES
			V2 (WEEK 4)	31	20AUG2009	YES	YES
			V3 (WEEK 12)	85	13OCT2009	YES	YES
	012	1	SCREENING	-32	17JUN2010	YES	
			V1 (WEEK 0)	1	19JUL2010	YES	YES
			V2 (WEEK 4)	25	12AUG2010	YES	YES
			V3 (WEEK 12)	88	14OCT2010	YES	YES
			V4 (WEEK 24)	176	10JAN2011	YES	YES
			V5 (WEEK 36)	257	01APR2011	YES	YES
			V6 (WEEK 52)	361	14JUL2011	YES	YES
			V7 (WEEK 56)	396	18AUG2011	YES	YES
	014	4	SCREENING	-26	07OCT2009	YES	
			V1 (WEEK 0)	1	02NOV2009	YES	YES
			V2 (WEEK 4)	32	03DEC2009	YES	YES
			V3 (WEEK 12)	85	25JAN2010	YES	YES
			V4 (WEEK 24)	172	22APR2010	YES	YES
			V5 (WEEK 36)	256	15JUL2010	YES	YES
			V6 (WEEK 52)	361	28OCT2010	YES	YES
			V7 (WEEK 56)	396	02DEC2010	YES	YES
	015	4	SCREENING	-32	21JAN2010	YES	
			V1 (WEEK 0)	1	22FEB2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	015	4	V2 (WEEK 4)	29	22MAR2010	YES	YES
			V3 (WEEK 12)	85	17MAY2010	YES	YES
			V4 (WEEK 24)	162	02AUG2010	YES	YES
			V5 (WEEK 36)	248	27OCT2010	YES	YES
			V6 (WEEK 52)	365	21FEB2011	YES	YES
			V7 (WEEK 56)	394	22MAR2011	YES	YES
	017	5	SCREENING	-22	14JUL2009	YES	
			V1 (WEEK 0)	1	05AUG2009	YES	YES
			UNSCHEDULED	9	13AUG2009	YES	YES
			UNSCHEDULED	16	20AUG2009	YES	YES
			V2 (WEEK 4)	29	02SEP2009	YES	YES
			V3 (WEEK 12)	85	28OCT2009	YES	YES
			V4 (WEEK 24)	169	20JAN2010	YES	YES
			V5 (WEEK 36)	252	13APR2010	YES	YES
			V6 (WEEK 52)	364	03AUG2010	YES	YES
			V7 (WEEK 56)	392	31AUG2010	YES	YES
	019	5	SCREENING	-21	18NOV2009	YES	
			V1 (WEEK 0)	1	09DEC2009	YES	YES
			V2 (WEEK 4)	29	06JAN2010	YES	YES
			V3 (WEEK 12)	85	03MAR2010	YES	YES
			V4 (WEEK 24)	168	25MAY2010	YES	YES
			V5 (WEEK 36)	259	24AUG2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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13FEB2013

Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	019	5	V6 (WEEK 52)	364	07DEC2010	YES	YES
			V7 (WEEK 56)	399	11JAN2011	YES	YES
	023	4	SCREENING	-19	01JUL2010	YES	
			V1 (WEEK 0)	1	20JUL2010	YES	YES
			V2 (WEEK 4)	24	12AUG2010	YES	YES
			V3 (WEEK 12)	86	13OCT2010	YES	YES
			V4 (WEEK 24)	177	12JAN2011	YES	YES
			V5 (WEEK 36)	245	21MAR2011	YES	YES
			V6 (WEEK 52)	364	18JUL2011	YES	YES
			V7 (WEEK 56)	388	11AUG2011	YES	YES
	027	20	SCREENING	-21	30SEP2010	YES	
			V1 (WEEK 0)	1	21OCT2010	YES	YES
			V2 (WEEK 4)	29	18NOV2010	YES	YES
			V3 (WEEK 12)	92	20JAN2011	YES	YES
			V4 (WEEK 24)	174	12APR2011	YES	YES
			V5 (WEEK 36)	259	06JUL2011	YES	YES
			V6 (WEEK 52)	370	25OCT2011	YES	YES
			V7 (WEEK 56)	407	01DEC2011	YES	YES
	030	8	SCREENING	-7	18MAR2010	YES	
			V1 (WEEK 0)	1	25MAR2010	YES	YES
			V2 (WEEK 4)	28	21APR2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	030	8	V3 (WEEK 12)	85	17JUN2010	YES	YES
			V4 (WEEK 24)	163	03SEP2010	YES	YES
			V5 (WEEK 36)	253	02DEC2010	YES	YES
			V6 (WEEK 52)	355	14MAR2011	YES	YES
			V7 (WEEK 56)	383	11APR2011	YES	YES
	032	8	SCREENING	-10	08NOV2010	YES	
			V1 (WEEK 0)	1	18NOV2010	YES	YES
			V2 (WEEK 4)	30	17DEC2010	YES	YES
			V3 (WEEK 12)	82	07FEB2011	YES	YES
	033	9	SCREENING	-7	28OCT2009	YES	
			V1 (WEEK 0)	1	04NOV2009	YES	YES
			V2 (WEEK 4)	29	02DEC2009	YES	YES
			V3 (WEEK 12)	78	20JAN2010	YES	YES
			V4 (WEEK 24)	169	21APR2010	YES	YES
			V5 (WEEK 36)	261	22JUL2010	YES	YES
			V6 (WEEK 52)	372	10NOV2010	YES	YES
			V7 (WEEK 56)	398	06DEC2010	YES	YES
	042	12	SCREENING	-29	16DEC2009	YES	
			V1 (WEEK 0)	1	14JAN2010	YES	YES
			V2 (WEEK 4)	29	11FEB2010	YES	YES
			V3 (WEEK 12)	126	19MAY2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	042	12	V4 (WEEK 24)	168	30JUN2010	YES	YES
			V5 (WEEK 36)	252	22SEP2010	YES	YES
			V6 (WEEK 52)	364	12JAN2011	YES	YES
			V7 (WEEK 56)	391	08FEB2011	YES	YES
	043	12	SCREENING	-28	21OCT2009	YES	
			V1 (WEEK 0)	1	18NOV2009	YES	YES
			V2 (WEEK 4)	29	16DEC2009	YES	YES
			V3 (WEEK 12)	85	10FEB2010	YES	YES
			V4 (WEEK 24)	176	12MAY2010	YES	YES
			V6 (WEEK 52)	267	11AUG2010	YES	YES
	046	11	SCREENING	-28	14DEC2009	YES	
			UNSCHEDULED	-21	21DEC2009	YES	YES
			V1 (WEEK 0)	1	11JAN2010	YES	YES
			V2 (WEEK 4)	29	08FEB2010	YES	YES
			V3 (WEEK 12)	87	07APR2010	YES	YES
			V4 (WEEK 24)	178	07JUL2010	YES	YES
			V5 (WEEK 36)	255	22SEP2010	YES	YES
			V6 (WEEK 52)	367	12JAN2011	YES	YES
			V7 (WEEK 56)	393	07FEB2011	YES	YES
	048	11	SCREENING	-5	17NOV2010	YES	
			V1 (WEEK 0)	1	22NOV2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	048	11	V2 (WEEK 4)	30	21DEC2010	YES	YES
			V3 (WEEK 12)	86	15FEB2011	YES	YES
			V4 (WEEK 24)	176	16MAY2011	YES	YES
			V5 (WEEK 36)	247	26JUL2011	YES	YES
			V6 (WEEK 52)	360	16NOV2011	YES	YES
			V7 (WEEK 56)	395	21DEC2011	YES	YES
	050	21	SCREENING	-51	06SEP2010	YES	
			V1 (WEEK 0)	1	27OCT2010	YES	YES
			V2 (WEEK 4)	27	22NOV2010	YES	YES
			V3 (WEEK 12)	83	17JAN2011	YES	YES
			V4 (WEEK 24)	167	11APR2011	YES	YES
			UNSCHEDULED	211	25MAY2011	YES	YES
			V5 (WEEK 36)	251	04JUL2011	YES	YES
			V6 (WEEK 52)	363	24OCT2011	YES	YES
			UNSCHEDULED	366	27OCT2011	YES	YES
			V7 (WEEK 56)	391	21NOV2011	YES	YES
	052	21	SCREENING	-52	06SEP2010	YES	
			V1 (WEEK 0)	1	28OCT2010	YES	YES
			V2 (WEEK 4)	27	23NOV2010	YES	YES
			V3 (WEEK 12)	82	17JAN2011	YES	YES
			V4 (WEEK 24)	166	11APR2011	YES	YES
			V5 (WEEK 36)	250	04JUL2011	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	052	21	V6 (WEEK 52)	362	24OCT2011	YES	YES
			V7 (WEEK 56)	390	21NOV2011	YES	YES
	055	5	SCREENING	-21	08MAR2010	YES	
			V1 (WEEK 0)	1	29MAR2010	YES	YES
			UNSCHEDULED	2	30MAR2010	YES	YES
			V6 (WEEK 52)	30	27APR2010	YES	YES
	057	1	SCREENING	-21	29JUL2010	YES	
			V1 (WEEK 0)	1	19AUG2010	YES	YES
			V2 (WEEK 4)	33	20SEP2010	YES	YES
			V3 (WEEK 12)	82	08NOV2010	YES	YES
			V4 (WEEK 24)	170	04FEB2011	YES	YES
	066	16	SCREENING	-31	09AUG2010	YES	
			UNSCHEDULED	-3	06SEP2010	YES	YES
			V1 (WEEK 0)	1	09SEP2010	YES	YES
			V2 (WEEK 4)	28	06OCT2010	YES	YES
			V3 (WEEK 12)	83	30NOV2010	YES	YES
	067	16	SCREENING	-16	02NOV2010	YES	
			UNSCHEDULED	-7	11NOV2010	YES	YES
			V1 (WEEK 0)	1	18NOV2010	YES	YES
			V2 (WEEK 4)	29	16DEC2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	067	16	V6 (WEEK 52)	69	25JAN2011	YES	YES
			V7 (WEEK 56)	111	08MAR2011	YES	YES
	071	18	SCREENING	-20	20OCT2010	YES	
			V1 (WEEK 0)	1	09NOV2010	YES	YES
			V2 (WEEK 4)	24	02DEC2010	YES	YES
			V3 (WEEK 12)	87	03FEB2011	YES	YES
			UNSCHEDULED	99	15FEB2011	YES	YES
			UNSCHEDULED	155	12APR2011	YES	YES
			V4 (WEEK 24)	177	04MAY2011	YES	YES
			V5 (WEEK 36)	253	19JUL2011	YES	YES
			V6 (WEEK 52)	374	17NOV2011	YES	YES
			V7 (WEEK 56)	392	05DEC2011	YES	YES
	080	13	SCREENING	-10	08NOV2010	YES	
			V1 (WEEK 0)	1	18NOV2010	YES	YES
			V2 (WEEK 4)	26	13DEC2010	YES	YES
			UNSCHEDULED	42	29DEC2010	YES	YES
			V3 (WEEK 12)	84	09FEB2011	YES	YES
			V6 (WEEK 52)	196	01JUN2011	YES	YES
	081	17	SCREENING	-10	04OCT2010	YES	
			V1 (WEEK 0)	1	14OCT2010	YES	YES
			V2 (WEEK 4)	33	15NOV2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	YES	YES
			V4 (WEEK 24)	175	06APR2011	YES	YES
			V5 (WEEK 36)	250	20JUN2011	YES	YES
			V6 (WEEK 52)	376	24OCT2011	YES	YES
			V7 (WEEK 56)	405	22NOV2011	YES	NO
	083	17	SCREENING	-15	26OCT2010	YES	
			V1 (WEEK 0)	1	10NOV2010	YES	YES
			V2 (WEEK 4)	29	08DEC2010	YES	YES
			V3 (WEEK 12)	85	02FEB2011	YES	YES
			V4 (WEEK 24)	168	26APR2011	YES	YES
			V5 (WEEK 36)	258	25JUL2011	YES	NO
			V6 (WEEK 52)	365	09NOV2011	YES	YES
			V7 (WEEK 56)	392	06DEC2011	YES	YES
	087	16	SCREENING	-20	09NOV2010	YES	
			V1 (WEEK 0)	1	29NOV2010	YES	YES
			V2 (WEEK 4)	30	28DEC2010	YES	YES
			V3 (WEEK 12)	81	17FEB2011	YES	YES
			UNSCHEDULED	94	02MAR2011	YES	YES
			UNSCHEDULED	99	07MAR2011	YES	YES
			V4 (WEEK 24)	169	16MAY2011	YES	YES
			V5 (WEEK 36)	255	10AUG2011	YES	YES
			V6 (WEEK 52)	365	28NOV2011	YES	YES

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
ACI-91	087	16	V7 (WEEK 56)	395	28DEC2011	YES	YES
	089	5	SCREENING	-28	19OCT2010	YES	
			V1 (WEEK 0)	1	16NOV2010	YES	YES
			V2 (WEEK 4)	29	14DEC2010	YES	YES
			V3 (WEEK 12)	84	07FEB2011	YES	YES
			V4 (WEEK 24)	168	02MAY2011	YES	YES
			V5 (WEEK 36)	252	25JUL2011	YES	YES
			V6 (WEEK 52)	364	14NOV2011	YES	YES
			V7 (WEEK 56)	394	14DEC2011	YES	YES
	093	17	SCREENING	-3	29NOV2010	YES	
			V1 (WEEK 0)	1	02DEC2010	YES	YES
			V2 (WEEK 4)	35	05JAN2011	YES	YES
			V3 (WEEK 12)	86	25FEB2011	YES	YES
			V4 (WEEK 24)	173	23MAY2011	YES	YES
			V5 (WEEK 36)	258	16AUG2011	YES	NO
			V6 (WEEK 52)	370	06DEC2011	YES	YES
			V7 (WEEK 56)	392	28DEC2011	YES	YES
	097	12	SCREENING	-21	27OCT2010	YES	
			V1 (WEEK 0)	1	17NOV2010	YES	YES
			V2 (WEEK 4)	28	14DEC2010	YES	YES
			V3 (WEEK 12)	85	09FEB2011	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	001	1	SCREENING	-7	02APR2009	YES	
			V1 (WEEK 0)	1	09APR2009	YES	YES
			V2 (WEEK 4)	29	07MAY2009	YES	YES
			V3 (WEEK 12)	90	07JUL2009	YES	YES
			V4 (WEEK 24)	162	17SEP2009	YES	YES
			V5 (WEEK 36)	246	10DEC2009	YES	YES
			V6 (WEEK 52)	365	08APR2010	YES	YES
			V7 (WEEK 56)	393	06MAY2010	YES	YES
	003	1	SCREENING	-21	07MAY2009	YES	
			V1 (WEEK 0)	1	28MAY2009	YES	YES
			V2 (WEEK 4)	28	24JUN2009	YES	YES
			V3 (WEEK 12)	90	25AUG2009	YES	YES
			V4 (WEEK 24)	169	12NOV2009	YES	YES
			V5 (WEEK 36)	253	04FEB2010	YES	YES
	005	2	SCREENING	-16	19MAY2009	YES	
			V1 (WEEK 0)	1	04JUN2009	YES	YES
			V2 (WEEK 4)	27	30JUN2009	YES	YES
			V3 (WEEK 12)	83	25AUG2009	YES	YES
			V4 (WEEK 24)	168	18NOV2009	YES	YES
			V5 (WEEK 36)	258	16FEB2010	YES	YES
			V6 (WEEK 52)	364	02JUN2010	YES	NO
			V7 (WEEK 56)	400	08JUL2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	009	1	SCREENING	-33	06AUG2009	YES	
			V1 (WEEK 0)	1	08SEP2009	YES	YES
			V2 (WEEK 4)	30	07OCT2009	YES	YES
			V3 (WEEK 12)	94	10DEC2009	YES	YES
			V4 (WEEK 24)	178	04MAR2010	YES	YES
			V5 (WEEK 36)	246	11MAY2010	YES	YES
			V6 (WEEK 52)	361	03SEP2010	YES	YES
			V7 (WEEK 56)	389	01OCT2010	YES	YES
	011	1	SCREENING	-21	05NOV2009	YES	
			V1 (WEEK 0)	1	26NOV2009	YES	YES
			V2 (WEEK 4)	35	30DEC2009	YES	YES
			V3 (WEEK 12)	85	18FEB2010	YES	YES
			V4 (WEEK 24)	162	06MAY2010	YES	YES
			V5 (WEEK 36)	253	05AUG2010	YES	YES
			V6 (WEEK 52)	366	26NOV2010	YES	YES
			V7 (WEEK 56)	397	27DEC2010	YES	YES
	013	4	SCREENING	-30	17AUG2009	YES	
			V1 (WEEK 0)	1	16SEP2009	YES	YES
			V2 (WEEK 4)	29	14OCT2009	YES	YES
			V3 (WEEK 12)	85	09DEC2009	YES	YES
			V4 (WEEK 24)	170	04MAR2010	YES	YES
			V5 (WEEK 36)	247	20MAY2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	013	4	V6 (WEEK 52)	366	16SEP2010	YES	YES
			V7 (WEEK 56)	400	20OCT2010	YES	YES
	016	4	SCREENING	-28	01FEB2010	YES	
			V1 (WEEK 0)	1	01MAR2010	YES	YES
			V2 (WEEK 4)	29	29MAR2010	YES	NO
			V3 (WEEK 12)	80	19MAY2010	YES	YES
			V4 (WEEK 24)	162	09AUG2010	YES	YES
			V5 (WEEK 36)	253	08NOV2010	YES	YES
			V6 (WEEK 52)	365	28FEB2011	YES	YES
			V7 (WEEK 56)	403	07APR2011	YES	YES
	018	5	SCREENING	-20	03NOV2009	YES	
			V1 (WEEK 0)	1	23NOV2009	YES	YES
			V2 (WEEK 4)	29	21DEC2009	YES	YES
			V3 (WEEK 12)	86	16FEB2010	YES	YES
			V4 (WEEK 24)	170	11MAY2010	YES	YES
			V5 (WEEK 36)	247	27JUL2010	YES	YES
			V6 (WEEK 52)	366	23NOV2010	YES	YES
			V7 (WEEK 56)	387	14DEC2010	YES	YES
	020	5	SCREENING	-26	27JAN2010	YES	
			V1 (WEEK 0)	1	22FEB2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	024	4	SCREENING	-31	16JUL2010	YES	
			V1 (WEEK 0)	1	16AUG2010	YES	YES
			V2 (WEEK 4)	31	15SEP2010	YES	YES
			V3 (WEEK 12)	87	10NOV2010	YES	YES
			V4 (WEEK 24)	171	02FEB2011	YES	YES
			V5 (WEEK 36)	246	18APR2011	YES	YES
			V6 (WEEK 52)	358	08AUG2011	YES	YES
			V7 (WEEK 56)	393	12SEP2011	YES	YES
	028	20	SCREENING	-8	18NOV2010	YES	
			V1 (WEEK 0)	1	26NOV2010	YES	YES
			V2 (WEEK 4)	26	21DEC2010	YES	YES
			V3 (WEEK 12)	89	22FEB2011	YES	YES
			V4 (WEEK 24)	180	24MAY2011	YES	YES
			V5 (WEEK 36)	273	25AUG2011	YES	YES
			V6 (WEEK 52)	364	24NOV2011	YES	YES
			V7 (WEEK 56)	390	20DEC2011	YES	YES
	029	8	SCREENING	-3	26JAN2010	YES	
			V1 (WEEK 0)	1	29JAN2010	YES	YES
			V2 (WEEK 4)	34	03MAR2010	YES	YES
			V3 (WEEK 12)	82	20APR2010	YES	YES
			V4 (WEEK 24)	158	05JUL2010	YES	YES
			V5 (WEEK 36)	245	30SEP2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	029	8	V6 (WEEK 52)	369	01FEB2011	YES	YES
			V7 (WEEK 56)	391	23FEB2011	YES	YES
	031	8	SCREENING	-14	06MAY2010	YES	
			V1 (WEEK 0)	1	20MAY2010	YES	YES
			V2 (WEEK 4)	27	15JUN2010	NO	YES
			V3 (WEEK 12)	90	17AUG2010	YES	YES
			V4 (WEEK 24)	174	09NOV2010	YES	YES
			V5 (WEEK 36)	251	25JAN2011	YES	YES
			V6 (WEEK 52)	363	17MAY2011	YES	YES
			V7 (WEEK 56)	391	14JUN2011	YES	YES
	034	9	SCREENING	-22	24FEB2010	YES	
			V1 (WEEK 0)	1	18MAR2010	YES	YES
			V2 (WEEK 4)	27	13APR2010	YES	YES
			V3 (WEEK 12)	83	08JUN2010	YES	YES
			V4 (WEEK 24)	175	08SEP2010	YES	YES
			V5 (WEEK 36)	258	30NOV2010	YES	YES
			V6 (WEEK 52)	363	15MAR2011	YES	YES
			V7 (WEEK 56)	399	20APR2011	YES	YES
	041	12	SCREENING	-16	23SEP2009	YES	
			V1 (WEEK 0)	1	09OCT2009	YES	YES
			V2 (WEEK 4)	32	09NOV2009	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	041	12	V3 (WEEK 12)	89	05JAN2010	YES	YES
			V4 (WEEK 24)	167	24MAR2010	YES	YES
			V5 (WEEK 36)	251	16JUN2010	YES	YES
			V6 (WEEK 52)	363	06OCT2010	YES	YES
			V7 (WEEK 56)	392	04NOV2010	YES	YES
	044	12	SCREENING	-28	04NOV2009	YES	
			V1 (WEEK 0)	1	02DEC2009	YES	YES
			V2 (WEEK 4)	37	07JAN2010	YES	YES
			V3 (WEEK 12)	85	24FEB2010	YES	YES
			V4 (WEEK 24)	176	26MAY2010	YES	YES
			V5 (WEEK 36)	260	18AUG2010	YES	YES
			V6 (WEEK 52)	365	01DEC2010	YES	YES
			V7 (WEEK 56)	400	05JAN2011	YES	YES
	045	11	SCREENING	-14	07DEC2009	YES	
			V1 (WEEK 0)	1	21DEC2009	YES	YES
			V2 (WEEK 4)	29	18JAN2010	YES	YES
			V3 (WEEK 12)	85	15MAR2010	YES	YES
			V4 (WEEK 24)	169	07JUN2010	YES	YES
			V5 (WEEK 36)	260	06SEP2010	YES	YES
			V6 (WEEK 52)	360	15DEC2010	YES	YES
			V7 (WEEK 56)	393	17JAN2011	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	047	11	SCREENING	-21	12JUL2010	YES	
			V1 (WEEK 0)	1	02AUG2010	YES	YES
			V2 (WEEK 4)	29	30AUG2010	YES	YES
			V3 (WEEK 12)	80	20OCT2010	YES	YES
			V4 (WEEK 24)	162	10JAN2011	YES	YES
			V5 (WEEK 36)	254	12APR2011	YES	YES
			V6 (WEEK 52)	360	27JUL2011	YES	YES
			V7 (WEEK 56)	393	29AUG2011	YES	YES
	049	21	SCREENING	-51	06SEP2010	YES	
			V1 (WEEK 0)	1	27OCT2010	YES	YES
			V2 (WEEK 4)	27	22NOV2010	YES	YES
			V3 (WEEK 12)	84	18JAN2011	YES	YES
			V4 (WEEK 24)	168	12APR2011	YES	YES
			UNSCHEDULED	213	27MAY2011	YES	YES
			V5 (WEEK 36)	252	05JUL2011	YES	YES
			UNSCHEDULED	258	11JUL2011	YES	YES
			UNSCHEDULED	267	20JUL2011	YES	YES
			UNSCHEDULED	274	27JUL2011	YES	YES
			UNSCHEDULED	286	08AUG2011	YES	YES
			UNSCHEDULED	302	24AUG2011	YES	YES
	051	21	SCREENING	-52	06SEP2010	YES	
			V1 (WEEK 0)	1	28OCT2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	051	21	V2 (WEEK 4)	27	23NOV2010	YES	YES
			V3 (WEEK 12)	97	01FEB2011	YES	YES
			V4 (WEEK 24)	167	12APR2011	YES	YES
			V5 (WEEK 36)	251	05JUL2011	YES	YES
			V6 (WEEK 52)	363	25OCT2011	YES	YES
			V7 (WEEK 56)	391	22NOV2011	YES	YES
	056	5	SCREENING	-21	31MAR2010	YES	
			V1 (WEEK 0)	1	21APR2010	YES	YES
			V2 (WEEK 4)	29	19MAY2010	YES	YES
			V3 (WEEK 12)	84	13JUL2010	YES	YES
			V4 (WEEK 24)	168	05OCT2010	YES	YES
			V5 (WEEK 36)	259	04JAN2011	YES	YES
			V6 (WEEK 52)	364	19APR2011	YES	YES
			V7 (WEEK 56)	393	18MAY2011	YES	YES
	058	1	SCREENING	-21	06DEC2010	YES	
			V1 (WEEK 0)	1	27DEC2010	YES	YES
			V2 (WEEK 4)	26	21JAN2011	YES	YES
			V3 (WEEK 12)	93	29MAR2011	YES	YES
			V4 (WEEK 24)	166	10JUN2011	YES	YES
			V5 (WEEK 36)	260	12SEP2011	YES	YES
			V6 (WEEK 52)	345	06DEC2011	YES	YES
			V7 (WEEK 56)	380	10JAN2012	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	059	1	SCREENING	-2	27DEC2010	YES	
			V1 (WEEK 0)	1	29DEC2010	YES	YES
			V2 (WEEK 4)	24	21JAN2011	YES	YES
			V3 (WEEK 12)	93	31MAR2011	YES	YES
			V4 (WEEK 24)	161	07JUN2011	YES	YES
			V5 (WEEK 36)	254	08SEP2011	YES	YES
			V6 (WEEK 52)	345	08DEC2011	YES	YES
			V7 (WEEK 56)	380	12JAN2012	YES	YES
	065	16	SCREENING	-20	10AUG2010	YES	
			V1 (WEEK 0)	1	30AUG2010	YES	YES
			V2 (WEEK 4)	29	27SEP2010	YES	YES
			V3 (WEEK 12)	85	22NOV2010	YES	YES
			V4 (WEEK 24)	141	17JAN2011	YES	YES
	068	16	SCREENING	-27	26OCT2010	YES	
			V1 (WEEK 0)	1	22NOV2010	YES	YES
			V2 (WEEK 4)	29	20DEC2010	YES	YES
			V3 (WEEK 12)	81	10FEB2011	YES	YES
			V4 (WEEK 24)	163	03MAY2011	YES	YES
			V5 (WEEK 36)	262	10AUG2011	YES	YES
			V6 (WEEK 52)	372	28NOV2011	YES	YES
			V7 (WEEK 56)	414	09JAN2012	YES	YES

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	069	23	SCREENING	-13	24NOV2010	YES	
			V1 (WEEK 0)	1	07DEC2010	YES	YES
			V2 (WEEK 4)	37	12JAN2011	YES	YES
			V3 (WEEK 12)	93	09MAR2011	YES	YES
			V4 (WEEK 24)	164	19MAY2011	YES	YES
			V5 (WEEK 36)	261	24AUG2011	YES	YES
			V6 (WEEK 52)	373	14DEC2011	YES	YES
			V7 (WEEK 56)	401	11JAN2012	YES	YES
	072	18	SCREENING	-20	01DEC2010	YES	
			V1 (WEEK 0)	1	21DEC2010	YES	YES
			V2 (WEEK 4)	31	20JAN2011	YES	YES
			V3 (WEEK 12)	85	15MAR2011	YES	YES
			V4 (WEEK 24)	169	07JUN2011	YES	YES
			V5 (WEEK 36)	262	08SEP2011	YES	YES
			V6 (WEEK 52)	360	15DEC2011	YES	YES
			V7 (WEEK 56)	393	17JAN2012	YES	YES
	079	13	SCREENING	-18	19JUL2010	YES	
			V1 (WEEK 0)	1	06AUG2010	YES	YES
			V2 (WEEK 4)	34	08SEP2010	YES	YES
			V3 (WEEK 12)	96	09NOV2010	YES	YES
			V4 (WEEK 24)	175	27JAN2011	YES	YES
			V5 (WEEK 36)	249	11APR2011	YES	YES

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	079	13	V6 (WEEK 52)	320	21JUN2011	YES	YES
			V7 (WEEK 56)	348	19JUL2011	YES	YES
	082	17	SCREENING	-8	06OCT2010	YES	
			V1 (WEEK 0)	1	14OCT2010	YES	YES
			V2 (WEEK 4)	35	17NOV2010	YES	YES
			V3 (WEEK 12)	84	05JAN2011	YES	YES
			V4 (WEEK 24)	175	06APR2011	YES	YES
			V5 (WEEK 36)	252	22JUN2011	YES	YES
			V6 (WEEK 52)	364	12OCT2011	YES	YES
			V7 (WEEK 56)	407	24NOV2011	YES	YES
	084	17	SCREENING	-9	08NOV2010	YES	
			V1 (WEEK 0)	1	17NOV2010	YES	YES
			V2 (WEEK 4)	29	15DEC2010	YES	YES
			V3 (WEEK 12)	84	08FEB2011	YES	YES
			V4 (WEEK 24)	175	10MAY2011	NO	YES
			V5 (WEEK 36)	259	02AUG2011	YES	YES
			V6 (WEEK 52)	371	22NOV2011	YES	YES
			V7 (WEEK 56)	394	15DEC2011	YES	YES
	086	21	SCREENING	-24	04OCT2010	YES	
			V1 (WEEK 0)	1	28OCT2010	YES	YES
			V2 (WEEK 4)	27	23NOV2010	YES	YES

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Listing 16.2.10.2: Prior/concomitant medication / adverse events questioning

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	Asked about conmed	Asked about AEs
Placebo	086	21	V3 (WEEK 12)	83	18JAN2011	YES	YES
			V4 (WEEK 24)	167	12APR2011	YES	YES
			V5 (WEEK 36)	251	05JUL2011	YES	YES
			V6 (WEEK 52)	363	25OCT2011	YES	YES
			V7 (WEEK 56)	391	22NOV2011	YES	YES
	088	16	SCREENING	-9	30NOV2010	YES	
			V1 (WEEK 0)	1	09DEC2010	YES	YES
			V2 (WEEK 4)	27	04JAN2011	YES	YES
			V3 (WEEK 12)	83	01MAR2011	YES	YES
			V4 (WEEK 24)	162	19MAY2011	YES	YES
			V5 (WEEK 36)	264	29AUG2011	YES	YES
			V6 (WEEK 52)	376	19DEC2011	YES	YES
			V7 (WEEK 56)	404	16JAN2012	YES	YES

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Listing 16.2.10.3: Comments

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	002	1	SCREENING	-7	16APR2009	COMMENTS	DATE OF SUMMARY IS 23/04/2009 COAGULATION TEST NOT DONE. VALUES FROM SCREENING VISIT ARE SUFFICIENT FOR LUMBAR PUNCTURE.
			V1 (WEEK 0)	1	23APR2009	COAGULATION TEST	
	004	1	V3 (WEEK 12)	92	15OCT2009	COMMENTS	DURING VISIT 3 THE PATIENT AND HIS WIFE REFUSED TO CONTINUE THIS STUDY. TELEPHONE CALL ON 29.10.09: WIFE REFUSED TO COME TO AN EARLY TERMINATION VISIT.
	006	2	V1 (WEEK 0)	1	26FEB2010	REPORT FROM FORMER MRI ASSESSMENT	A MRI WAS PERFORMED ON 02.02.2010 BETWEEN SCREENING VISIT AND VISIT 1.
	010	1	SCREENING	-26	25JUN2009	12-LEAD ECG-EVALUATION	ON SCREENING DAY ECG RECORDING TECHNICAL NOT POSSIBLE, SO PERFORMED ON THE FOLLOWING DAY. COAGULATION TEST NOT DONE. VALUES FROM SCREENING VISIT ARE SUFFICIENT FOR LUMBAR PUNCTURE. EMPTY BLISTERS DISCHARGED BY PATIENT
			V1 (WEEK 0)	1	21JUL2009	COAGULATION TEST	
			V2 (WEEK 4)	31	20AUG2009	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	012	1	V1 (WEEK 0)	1	19JUL2010	COAGULATION TEST	COGULATION TEST WAS NOT DONE AS LAB RESULT FROM SCREENING ARE SUFFICIENT.
			V3 (WEEK 12)	88	14OCT2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	PATIENT USED 128 TABLETS ACC. THE DIARY, BUT RETURNED 63 TABLETS. THIS HAPPENED BECAUSE THE REMAINING MEDICATION OF VISIT 1 WAS TAKEN. THEREFORE APPR. 30 TABLETS WERE NOT TAKEN FROM THE PATIENT. THE CAREGIVER WAS INFORMED AND ASKED TO CHECK THE CORRECT INTAKE IN THE FUTURE.
						COAGULATION TEST	BECAUSE PATIENT REFUSED LUMBAR PUNCTION NO COAGULATION TEST AND NEW MRI WAS NECESSARY.
						QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST NOT DONE BECAUSE PATIENT REFUSED THE TEST.
			V4 (WEEK 24)	176	10JAN2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY BLOOD SAMPLING	EMPTY BLISTERS AND TWO EMPTY BOXES WERE THROWN AWAY BY PATIENT. INCREASED GOT AND GPT VALUES AT VISIT3 WERE ALREADY CONTROLLED BY THE GENERAL PRACTITIONER AT 29.11.2010. BOTH VALUES WERE IN NORMAL RANGES.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	012	1	V4 (WEEK 24)	176	10JAN2011	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1 AND 2 WERE NOT DONE. PATIENT REFUSED THE TESTS. A PROTOCOL DEVIATION FORM WAS WRITTEN.
			V5 (WEEK 36)	257	01APR2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY QUESTIONNAIRES AND TESTS	ONE EMPTY BLISTER THROWN AWAY BY PATIENT. SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1 AND 2 AND WECHSLER VERBAL PAIRED ASSOCIATES WERE NOT DONE. PATIENT REFUSED THE TESTS. A PROTOCOL DEVIATION FORM WAS WRITTEN.
			V6 (WEEK 52)	361	14JUL2011	QUESTIONNAIRES AND TESTS	PATIENT REFUSED SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1 AND 2.
			V7 (WEEK 56)	396	18AUG2011	12-LEAD ECG-EVALUATION 12-LEAD ECG-EVALUATION QUESTIONNAIRES AND TESTS	ANSWER NOT AVAILABLE NOT AVAILABLE FOR DATABASE ENTRY. REACTION TEST NOT DONE BECAUSE PATIENT REFUSED THE TEST
	014	4	SCREENING	-26	07OCT2009	12-LEAD ECG-EVALUATION	RESULT: T-NEGATIVATION IN III, AVF AND FLATTENED T IN V4-V6. ACCORDING TO OUR CARDIOLOGIST: NO SIGNIFICANT FINDING.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	015	4	V1 (WEEK 0)	1	22FEB2010	12-LEAD ECG-EVALUATION	BRADYCARDIA OF 49 B/MIN. ACCORDING TO OUR CARDIOLOGIST NO CONTRAINDICATION FOR THE CLINICAL STUDY .
			V3 (WEEK 12)	85	17MAY2010	COAGULATION TEST	LP NOT DONE, PATIENT REFUSED A RE-PUNCTURE.
			V5 (WEEK 36)	248	27OCT2010	URINE SAMPLING	URINANALYSIS WAS ORDERED TO CONTROL THE FINDINGS OF SCREENING VISIT AND VISIT 1 (LEUCOCYTES AND ERYTHROCYTES IN URINE) - THE PATIENT HAS NO SYMPTOMS OF UROGENITAL INFECTION.
			V6 (WEEK 52)	365	21FEB2011	BLOOD SAMPLING	BLOOD SAMPLING FOR HEMATOLOGY WAS PERFORMED BUT BLOOD WAS COAGULTED THEREFORE THE VALUES WERE MISSING.
	017	5	SCREENING	-22	14JUL2009	VITAL SIGNS	BLOOD PRESSURE STANDING NOT DONE COAGULATION TEST WAS PERFORMED 2 DAYS PRIOR TO LUMBAR PUNCTURE TO HAVE RESULTS READY
			V3 (WEEK 12)	85	28OCT2009	COAGULATION TEST	
	019	5	V1 (WEEK 0)	1	09DEC2009	COAGULATION TEST	RESULTS FROM 10/2009 WERE USED TO AVOID ANOTHER BLOOD DRAW

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	019	5	V1 (WEEK 0)	1	09DEC2009	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	PATIENT WAS ENROLLED INTO THE STUDY BECAUSE THE COAGULATION VALUES WERE NORMAL AT THE LOCAL LAB
			V4 (WEEK 24)	168	25MAY2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	ONLY 17 OF 21 BLISTERS WERE RETURNED. CAREGIVER REPORTED, THAT EMPTY BLISTERS WERE WASTED ACCIDENTIALLY BY THE PATIENT
	023	4	V3 (WEEK 12)	86	13OCT2010	COAGULATION TEST	PATIENT REFUSED TO BE LUMBAR PUNCTURED THEREFORE NO COAGULATION TEST WAS PERFORMED.
			V5 (WEEK 36)	245	21MAR2011	12-LEAD ECG-EVALUATION	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V6 (WEEK 52)	364	18JUL2011	12-LEAD ECG-EVALUATION	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V7 (WEEK 56)	388	11AUG2011	BLOOD SAMPLING	ASSESSMENT OF INVESTIGATOR NOT AVAILABLE
	027	20	SCREENING	-21	30SEP2010	RELEVANT MEDICAL & SURGICAL HISTORY (OTHER DISEASES THAN AD)	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V6 (WEEK 52)	370	25OCT2011	COMMENTS	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	027	20	V7 (WEEK 56)	407	01DEC2011	COMMENTS	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
	030	8	SCREENING	-7	18MAR2010	QUESTIONNAIRES AND TESTS	TMT B WAS NOT DONE BECAUSE PATIENT COULD NOT UNDERSTAND INSTRUCTIONS.
			V1 (WEEK 0)	1	25MAR2010	QUESTIONNAIRES AND TESTS	TMT B WAS NOT DONE BECAUSE PATIENT COULD NOT UNDERSTAND INSTRUCTIONS
			V3 (WEEK 12)	85	17JUN2010	COAGULATION TEST	COAGULATION TEST NOT PERFORMED BECAUSE NO CSF SAMPLING DONE.
						REPORT FROM FORMER MRI ASSESSMENT	MRI ASSESSMENT NOT DONE BECAUSE NO CSF SAMPLING PERFORMED.
						QUESTIONNAIRES AND TESTS	ADAS COG FORM B WAS NOT DONE DUE TO TASK DIFFICULTY.
						QUESTIONNAIRES AND TESTS	TMT B WAS NOT DONE BECAUSE PATIENT COULD NOT UNDERSTAND INSTRUCTIONS
			V5 (WEEK 36)	253	02DEC2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	ONE EMPTY BLISTER WAS NOT GIVEN BACK BY PATIENT.
	032	8	V3 (WEEK 12)	82	07FEB2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	COMMENT FROM COMMENT PAGE: PAT. DISPOSED ALL EMPTY BLISTERS OF IMP AND ONE WAS FORGOTTEN AT HOME.
						COMMENTS	PAT. EXCLUDED FROM STUDY, BECAUSE PAT. CAN'T FULLFIL THE STUDY PROCEDURE. NO EARLY TERMINATION VISIT PERFORMED.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	033	9	SCREENING	-7	28OCT2009	EXCLUSION CRITERIA	COAGULATION (PTT) AT SCREENING VISIT WAS HIGHER THAN NORM RANGE. HOWEVER COAGULATION TEST WAS REPEATED LOCALLY ON 04/NOV/2009 WITH NORMAL VALUES (PTT=25.8 SEC). THEREFORE PATIENT WAS ENROLLED INTO STUDY.
			V1 (WEEK 0)	1	04NOV2009	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	COAGULATION (PTT) AT SCREENING VISIT WAS HIGHER THAN NORM RANGE. HOWEVER COAGULATION TEST WAS REPEATED LOCALLY ON 04/NOV/2009 WITH NORMAL VALUES (PTT=25.8 SEC). THEREFORE PATIENT WAS ENROLLED INTO STUDY. A RESPECTIVE PROTOCOL DEVIATION FORM WAS PREPARED AND SIGNED.
			V3 (WEEK 12)	78	20JAN2010	PRIOR/CONCOMITANT MEDICATION/THERAPY VITAL SIGNS COAGULATION TEST ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	VISIT DATE CONFIRMED. PATIENT TOO EARLY DUE TO PERSONAL REASONS (HOLIDAYS) VALUES ARE CORRECT. THIS TEST WAS NOT DONE. NEW TABLETS WERE NOT YET AVAILABLE AND WERE COLLECTED LATER.

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ACI-91	033	9	V3 (WEEK 12)	78	20JAN2010	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	AS NEW MEDICATION FOR VISIT 3 WAS NOT AVAILABLE AT THE START OF VISIT 3 THE REMAINING TABLETS FROM VISIT 2 WERE REDISPENSED TO THE PATIENT.
						DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	AS AT THE TIME OF VISIT 3 NO NEW MEDICATION WAS AVAILABLE AT SITE, THE PATIENT WAS ALLOWED TO TAKE THE REMAINING MEDICATION OF VISIT 2 UNTIL NEW MEDICATION FOR VISIT 3 WAS RECEIVED AT THE SITE.
						ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	VISIT 3 MEDICATION WAS SHIPPED TO SITE 22-JAN-2010.
			V4 (WEEK 24)	169	21APR2010	QUESTIONNAIRES AND TESTS	TMT-B WAS DISCONTINUED PREMATURALLY DUE TO THE PATIENTS DISABILITY
			V5 (WEEK 36)	261	22JUL2010	QUESTIONNAIRES AND TESTS 12-LEAD ECG-EVALUATION	TMT-B WAS NOT DONE AT VISIT 5 ECG WAS FORGOTTEN TO PERFORM
						12-LEAD ECG-EVALUATION	TO DOCUMENT THE MISSING ECG A RESPECTIVE PROTOCOL DEVIATION FORM WAS CREATED AND SIGNED.
			V6 (WEEK 52)	372	10NOV2010	QUESTIONNAIRES AND TESTS	TMT PART B NOT DONE
			V7 (WEEK 56)	398	06DEC2010	QUESTIONNAIRES AND TESTS	TMT PART B NOT DONE

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	042	12	SCREENING	-29	16DEC2009	VITAL SIGNS PRIOR/CONCOMITANT MEDICATION/THERAPY	BODY WEIGHT WAS NOT MEASURED AT VS VISIT 1 WAS PERFORMED ONE DAY TOO LATE BECAUSE OF ORGANISATIONAL REASONS
			V1 (WEEK 0)	1	14JAN2010	CEREBROSPINAL FLUID SAMPLING	LUMBAR PUNKTION FAILED AT VISIT 1 (14/01/2010) AND WAS REPEATED ON 20/01/2010
			V3 (WEEK 12)	126	19MAY2010	PRIOR/CONCOMITANT MEDICATION/THERAPY	BECAUSE OF AN ACCIDENT WITH HOSPITALIZATION OF PATIENT'S HUSBAND SHE HAD TO STAY TEMPORARILY IN A NURSING HOME IN SOUTH GERMANY AND WAS THEREFORE NOT ABLE TO COME IN TIME TO VISIT 3. THE VISIT WAS SHIFTED AFTER CONSULTING OF STUDY MONITOR.
			V6 (WEEK 52)	364	12JAN2011		BY ASCCIDENT DATA FROM PATIENT 12-002 (CRF 43) WAS ENTERED IN THE THE CRF 070. THIS WILL BE OVERWRITTEN AT THE TIME PATIENT 12-004 (CRF 70) WILL REACH VISIT 6.
	043	12	SCREENING	-28	21OCT2009	REPORT FROM FORMER MRI ASSESSMENT	MRI WAS DONE ON 15TH OCT 2009 FOR STUDY REASONS
			V6 (WEEK 52)	267	11AUG2010	12-LEAD ECG-EVALUATION	NOT DONE

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ACI-91	043	12	V6 (WEEK 52)	267	11AUG2010	VITAL SIGNS	RR WAS EXAMINED IN LYING POSITION ONLY , IN STANDING POSITION NOT DONE
						COAGULATION TEST	NOT DONE
	046	11	SCREENING	-28	14DEC2009	INFORMED CONSENT	INITIALLY, THE SITE FORGOT TO INVOLVE AN INDEPENDENT PHYSICIAN IN THE INFORMED CONSENT PROCESS. DR. GUIDO STRATEN WAS ASKED TO ACT AS AN INDEPENDENT PHYSICIAN FOR THIS STUDY WHO LATER MET THE PATIENT AND SIGNED THE NEW VERSION 5.0 OF THE INFORMED CONSENT FORM. A PROTOCOL DEVIATION FORM FOR THIS ISSUE WAS CREATED AND SIGNED.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	046	11	SCREENING	-28	14DEC2009	EXCLUSION CRITERIA	THE PATIENT SHOWED CREATININE LEVELS ABOVE 1.5XULN AT THE SCREENING VISIT. CREATININE WAS RE-CHECKED DURING AN UNSCHEDULED VISIT BEFORE THE RANDOMIZATION AND REVEALED LEVELS NEAR NORMAL. THEREFORE THE PATIENT COULD BE RANDOMIZED DESPITE THE INCREASED LEVELS AT THE SCREENING VISIT. A PROTOCOL DEVIATION FORM FOR THIS ISSUE WAS CREATED AND SIGNED.
			V1 (WEEK 0)	1	11JAN2010	QUESTIONNAIRES AND TESTS	THE FOLLOWING TEST WERE NOT PERFORMED BECAUSE THE PATIENT WAS EXHAUSTED: CHOICE REACTION TASK 1, WECHSLER VERBAL PAIRED ASSOCIATES, COWAT, CATEGORY FLUENCY TEST, TRAIL MAKING TEST.
						ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	PATIENT WAS ENROLLED INTO STUDY DESPITE INCREASED CREATININE VALUES AT BASELINE VISIT. A RE-CHECK OF CREATININE WAS PERFORMED AT VISIT 1 WITH ACCEPTABLE VALUES.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	046	11	V1 (WEEK 0)	1	11JAN2010	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	THE PATIENT SHOWED CREATININE LEVELS ABOVE 1.5XULN AT THE SCREENING VISIT. CREATININE WAS RE-CHECKED DURING AN UNSCHEDULED VISIT BEFORE THE RANDOMIZATION AND REVEALED LEVELS NEAR NORMAL. THEREFORE THE PATIENT COULD BE RANDOMIZED DESPITE THE INCREASED LEVELS AT THE SCREENING VISIT. A PROTOCOL DEVIATION FORM FOR THIS ISSUE WAS CREATED AND SIGNED.
			V3 (WEEK 12)	87	07APR2010	COAGULATION TEST	NOT NECESSARY BECAUSE NO LUMBAR PUNCTURE HAS BEEN PERFORMED
			V5 (WEEK 36)	255	22SEP2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	ONE BLISTER CONTAINING 6 TABLETS WERE LOST AND THEREFORE NOT RETURNED TO THE SITE.
			V6 (WEEK 52)	367	12JAN2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	ONE EMPTY BLISTER WAS NOT RETURNED TO THE SITE.
			V7 (WEEK 56)	393	07FEB2011	QUESTIONNAIRES AND TESTS	TMT-B WAS STOPPED EARLIER DUE TO LACK OF UNDERSTANDING
	048	11	V2 (WEEK 4)	30	21DEC2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	ONE BLISTER CONTAINING FOUR REMAINING TABLETS WAS LOST AT HOME AND THEREFORE NOT RETURNED TO THE SITE.

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ACI-91	048	11	V3 (WEEK 12)	86	15FEB2011	COAGULATION TEST	COAGULATION WAS NOT DETERMINED BECAUSE NO LUMBAR PUNCTURE WAS DONE.
			V4 (WEEK 24)	176	16MAY2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY QUESTIONNAIRES AND TESTS	2 TABLETS GOT LOST DURING STUDY. IN ADDITION PATIENT FORGOT TO TAKE IN STUDY DRUG THREE TIMES. WECHSLER VERBAL PAIRED ASSOCIATES TEST WAS NOT DONE BECAUSE PATIENT DID NOT UNDERSTAND INSTRUCTIONS.
			V5 (WEEK 36)	247	26JUL2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	PATIENT FORGOT TO TAKE IN STUDY MEDICATION ONE TIME.
	050	21	V1 (WEEK 0)	1	27OCT2010	CEREBROSPINAL FLUID SAMPLING	PATIENT SIGNED HOSPITAL'S VERSION OF THE ICF FOR LUMBAR PUNCTURE. THE PATIENT WILL SIGN THE ICF (LUMBAR PUNCTURE) OF THE CASE REPORT FORM AT HIS NEXT VISIT.
	052	21	SCREENING	-52	06SEP2010	EXCLUSION CRITERIA EXCLUSION CRITERIA	SPONSOR APPROVED INCLUSION WITH ELEVATED PTT (43.6: 26.0-40.0). STATEMENT BY INVESTIGATOR ON LAB REPORT REG. SPONSOR APPROVAL AVAILABLE. NO ELEVATED VALUES FOR HIV, TPHA, VDRL AT VS.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	052	21	V1 (WEEK 0)	1	28OCT2010	CEREBROSPINAL FLUID SAMPLING	PATIENT SIGNED HOSPITAL'S VERSION OF THE ICF FOR LUMBAR PUNCTURE. THE PATIENT WILL SIGN THE ICF (LUMBAR PUNCTURE) OF THE CASE REPORT FORM AT HIS NEXT VISIT.
			V6 (WEEK 52)	362	24OCT2011	REPORT FROM FORMER MRI ASSESSMENT	THE SITE FORGOT THAT THE MRI NEEDS TO BE DONE BEFORE THE LUMBAR PUNCTURE. A PROTOCOL DEVIATION FORM WILL BE FILLED IN AND FILED WITHIN THE PATIENT BINDER.
	055	5	V6 (WEEK 52)	30	27APR2010	GLOBAL ASSESSMENT OF TOLERABILITY (ASSESSMENT BY INVESTIGATOR) DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	ASSESSMENT NOT DONE BECAUSE PATIENT DID NOT TAKE IMP SINCE LAST VISIT. ASSESSMENT DOES NOT APPLY. THE PATIENT DIARY WAS NOT RETURNED BY THE PATIENT. REACTION TEST NOT DONE.
	057	1	SCREENING	-21	29JUL2010	COMMENTS	MRI ASSESSMENT AVAILABLE (DONE WITHIN 1 YEAR) BUT OLDER THAN 4 MONTHS AT TIME OF V1, SO NEW MRI ASSESSMENT DONE ON 29 JULY 2010.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	057	1	SCREENING	-21	29JUL2010	QUESTIONNAIRES AND TESTS	THE PATIENT WAS NOT ABLE TO PERFORM THE COMPLETE TEST, SEE PROTOCOL DEVIATION FORM.
						RELEVANT MEDICAL & SURGICAL HISTORY (OTHER DISEASES THAN AD)	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION.
			V1 (WEEK 0)	1	19AUG2010	COAGULATION TEST	COAGULATION TEST NOT DONE. VALUES FROM SCREENING VISIT ARE SUFFICIENT FOR LUMBAR PUNCTURE.
						QUESTIONNAIRES AND TESTS	THE PATIENT WAS NOT ABLE TO PERFORM THE COMPLETE TEST, SEE PROTOCOL DEVIATION FORM.
			V3 (WEEK 12)	82	08NOV2010	COAGULATION TEST	PATIENT REFUSED FLUID SAMPLING, SO COAGULATION TEST AND NEW MRI WAS NOT PERFORMED.
						REPORT FROM FORMER MRI ASSESSMENT	PATIENT REFUSED FLUID SAMPLING, SO COAGULATION TEST AND NEW MRI WAS NOT PERFORMED
						ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	NEW TABLETS ARE STILL IN GRUENSTADT (CRS MANNHEIM), SO 44 TABLETS (RETURNED) ARE DISPENDED

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ACI-91	057	1	V3 (WEEK 12)	82	08NOV2010	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY QUESTIONNAIRES AND TESTS	NEW 210 TABLETS FOR VISIT 3 WILL BE SENT TO THE PATIENT IN THE NEXT DAYS. THE PATIENT WAS NOT ABLE TO PERFORM THE COMPLETE TEST, SEE PROTOCOL DEVIATION FORM.
			V4 (WEEK 24)	170	04FEB2011	NEUROLOGICAL EXAMINATION DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY QUESTIONNAIRES AND TESTS	SIGNS OF APRAXIA AS A SYMPTOM OF THE ALZHEIMER DISEASE AT VISIT 4 THE PATIENT RETURNED THE REMAINING STUDY MEDICATION OF VISIT 2 AND VISIT 3. THE PATIENT WAS NOT ABLE TO PERFORM THE COMPLETE TEST, SEE PROTOCOL DEVIATION FORM.
	066	16	SCREENING	-31	09AUG2010	REPORT FROM FORMER MRI ASSESSMENT	MRI PERFORMED ON 19.11.2009 AND ON 17.08.2010.
			V3 (WEEK 12)	83	30NOV2010	COAGULATION TEST	OPTIONAL LP-NOT DONE
	067	16	V6 (WEEK 52)	69	25JAN2011	COMMENTS	EARLY TERMINATION DUE TO ADVERSE EVENTS. DATE OF LAST IMP-DOSE: 31-12-2010

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ACI-91	071	18	SCREENING	-20	20OCT2010	EXCLUSION CRITERIA	IN LOCAL LAB THE PPT WAS IN RANGE. PTT 35,3, QUICK (TPZ) 87: INR 1.07.
			V3 (WEEK 12)	87	03FEB2011	COAGULATION TEST	COAGULATION TEST NOT PERFORMED BECAUSE NO LP PERFORMED.
			V6 (WEEK 52)	374	17NOV2011	REPORT FROM FORMER MRI ASSESSMENT	MRI ASSESSMENT NOT NECESSARY BECAUSE NO LP PERFORMED.
						CEREBROSPINAL FLUID SAMPLING	OPTIONAL
						DISPENSING OF PATIENT DIARY	DIARY OF V5 WAS DISPENSED AGAIN THAT PATIENT CAN WRITE IN ADVERSE EVENTS (IF NEEDED). NO NEW DIARY DISPENSED.
						QUESTIONNAIRES AND TESTS	THE FOLLOWING TESTS WERE NOT PERFORMED AS PATIENT COGNITIVELY LIMITED: WECHSLER VERBAL PAIRED ASSOCIATES COWAT(FAS) CATEGORY FLUENCY TEST TRAIL MAKING TEST
			V7 (WEEK 56)	392	05DEC2011	REVIEW OF PATIENT DIARY	REVIEW OF PATIENT DIARY ONLY FOR AES.
	080	13	V1 (WEEK 0)	1	18NOV2010		TESTS WERE PERFORMED ONE DAY AFTER VISIT DATE

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ACI-91	080	13	V1 (WEEK 0)	1	18NOV2010	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	PAGE 27 OF THE CRF NO. 59 WAS NOT AVAILABLE AT SITE. THEREFORE A COPY OF PAGE 27 FROM ANOTHER CRF WAS MADE AND THE ENTRIES WERE DONE BY THE SITE USING A NORMAL BALL PEN. THIS DATA WAS ENTERED INTO THE ECRF MANUALLY (WITHOUT DATA TRANSFER) BY THE MONITOR ON 05.01.2011.
			V6 (WEEK 52)	196	01JUN2011	GLOBAL ASSESSMENT OF TOLERABILITY (ASSESSMENT BY INVESTIGATOR)	GLOBAL ASSESMENT NOT APPLICABLE AS STUDY MEDICATION HAS ALREADY BEEN STOPPED DUE TO SAE
	081	17	V1 (WEEK 0)	1	14OCT2010	URINE SAMPLING	NO URINE SAMPLING PERFORMED BY MISTAKE. A PROTOCOL DEVIATION FORM WAS WRITTEN.
						COMMENTS	ORIGINAL DIARY LOST BY PATIENT AND CAREGIVER. A COPY OF DIARY VISIT 1 WAS USED.
			V2 (WEEK 4)	33	15NOV2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	PATIENT DID NOT BRING BACK EMPTY BLISTER
			V3 (WEEK 12)	89	10JAN2011	COAGULATION TEST	NOT DONE BECAUSE NO CSF SAMPLING WAS PERFORMED.
						REPORT FROM FORMER MRI ASSESSMENT	NO MRI ASSESSMENT WAS PERFORMED BECAUSE NO CSF SAMPLING WAS DONE.

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ACI-91	081	17	V3 (WEEK 12)	89	10JAN2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	EMPTY BLISTER WERE THRAWN AWAY BY CAREGIVER.
			V4 (WEEK 24)	175	06APR2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	EMPTY BLISTER WERE THROWN AWAY BY CAREGIVER.
			V6 (WEEK 52)	376	24OCT2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	EMPTY BLISTERS WERE THRAWN AWAY.
	083	17	SCREENING	-15	26OCT2010	RELEVANT MEDICAL & SURGICAL HISTORY (OTHER DISEASES THAN AD)	HYPERCHOLESTEROLEMIA WITH START DATE 1998 BUT ACCORDING TO CONCOMITANT MEDICATION ALREADY TREATED IN 1995: FIRST SYMPTOMES STARTED 1995, BUT FIRST DIAGNOSIS 1998
						RELEVANT MEDICAL & SURGICAL HISTORY (OTHER DISEASES THAN AD)	HYPERTENSION WITH START DATE 2000 BUT ACCORDING TO CONCOMITANT MEDICATION ALREADY TREATED IN 1998: FIRST SYPTOMES ALREADY 1998, BUT OFFICEL DIAGNOSIS INTO 2000
			V2 (WEEK 4)	29	08DEC2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	DIARY VISIT 1 MISSING
			V3 (WEEK 12)	85	02FEB2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	4 BLISTERS ARE MISSING

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	083	17	V3 (WEEK 12)	85	02FEB2011	COAGULATION TEST	COAGULATION TEST NOT PERFORMED BECAUSE PATIENT REFUSED EXAMINATION. SEE PROTOCOL DEVIATION.
						12-LEAD ECG-EVALUATION	NO ECG WAS PERFORMED BECAUSE PATIENT REFUSED EXAMINATION. A PROTOCOL DEVIATION FORM WAS FILLED IN.
			V5 (WEEK 36)	258	25JUL2011	12-LEAD ECG-EVALUATION	ECG WAS NOT PERFORMED AS PATIENT REFUSED
	087	16	SCREENING	-20	09NOV2010	COMMENTS	PATIENT FURTHER FORGETFUL AND CHANGEABLE, ESPECIALLY SHORT TIME-MEMORY. REPEATS THINGS OFTEN, STILL VERY INDEPENDENT ONLY COOKING DOES NOT WORK ANYMORE. SYMPTOMS SINCE 2006 TO 2007 AT THE LATEST.
			V1 (WEEK 0)	1	29NOV2010	COAGULATION TEST	ACCORDING TO QUERY-ANSWER: COAGULATION TEST WAS DONE AT SCREENING VISIT
			V3 (WEEK 12)	81	17FEB2011	COAGULATION TEST REPORT FROM FORMER MRI ASSESSMENT	WAS OPTIONAL LP- NOT DONE DUE TO OPTIONAL LP- NOT DONE

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	087	16	V3 (WEEK 12)	81	17FEB2011	COMMENTS	BECAUSE OF CONSIDERABLE DECREASE OF COGNITIVE ABILITIES, DISCUSSION OF ELEVATION OF DONEPEZIL TO 10 MG. AGREEMENT WITH JULIAN GRAY (19.FEBR. 2011) INCREASE OF DOSIS AFTER COMPLETE NEUROPSYCHOLOGICAL ASSESSMENT.
			V4 (WEEK 24)	169	16MAY2011	COMMENTS	PAT. HAD MOSTLY ELEVATED EOSINOPHILS. IN SOME VISITS ALSO ELEVATED BASOPHILS. WORSENING OF FORGETFULNESS, PERSONAL HYGIENE INDEPENDENTLY. INCREASED UNREST IN THE EVENING (SUNDOWNING), HAS TO CHECK EVERYTHING. SEARCHES REGULARLY CLOTHES, KEYS ETC...
			V6 (WEEK 52)	365	28NOV2011	COAGULATION TEST	FIRST RUNAWAY ON EASTER. THE DATE OF COAGULATION IS CORRECT 21-NOV-2011
			V7 (WEEK 56)	395	28DEC2011	COMMENTS	TENDENCY FOR WORSENING OF DEMENTIA SYNDROM DURING THE STUDY. ID WAS WELL TOLERATED.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	089	5	SCREENING	-28	19OCT2010	INFORMED CONSENT	VERSION V 0.05 WAS SIGNED INSTEAD OF V 0.06. ACCORDING TO INVESTIGATOR THE PATIENT WAS INFORMED WITH THE LATEST STUDY INFORMATION BUT ACCIDENTIALLY THE WRONG VERSION WAS SIGNED. PATIENT AND INVESTIGATOR SHALL SIGN ICF VERSION V 0.06 AS SOON AS POSSIBLE.
			V1 (WEEK 0)	1	16NOV2010	COAGULATION TEST	VALUES FROM VS WERE USED TO ASSESS SAFETY OF LUMBAR PUNCTURE. IN THE OPINION OF THE INVESTIGATOR A DETERIOATION IS NOT TO BE EXPECTED DURING 4 WEEKS.
			V3 (WEEK 12)	84	07FEB2011	COAGULATION TEST	PATIENT WAS TOO AGITATED FOR LUMBAR PUNCTURE, THEREFOR NO COAGULATION TEST WAS DONE
						REPORT FROM FORMER MRI ASSESSMENT	PATIENT WAS TOO AGITATED FOR LUMBAR PUNCTURE, THEREFOR NO SAFETY MRI WAS PERFORMED
						DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	DIARY VISIT 3 IS MISSING
			V5 (WEEK 36)	252	25JUL2011	QUESTIONNAIRES AND TESTS	REACTION TEST NOT DONE.
			V6 (WEEK 52)	364	14NOV2011	QUESTIONNAIRES AND TESTS	REACTION TEST NOT DONE.
			V7 (WEEK 56)	394	14DEC2011	QUESTIONNAIRES AND TESTS	REACTION TEST NOT DONE.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
ACI-91	093	17	SCREENING	-3	29NOV2010	INCLUSION CRITERIA	MMSE AT SCREENING WAS ONLY 17. HOWEVER, THE MMSE AT VISIT 1 (3 DAYS AFTER SCREENING) WAS 19 AND THEREFORE, PATIENT WAS ENROLLED. PROTOCOL DEVIATION WRITTEN.
			V2 (WEEK 4)	35	05JAN2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	HUSBAND OF PATIENT PUT AWAY THE BLISTERS FROM VISIT 1 AS THEY WERE EMPTY
			V3 (WEEK 12)	86	25FEB2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	IN TOTAL 9 EMPTY BLISTERS AND 1 EMPTY PACKAGE WAS NOT RETURNED TO THE SITE
			V5 (WEEK 36)	258	16AUG2011	12-LEAD ECG-EVALUATION	NO ECG PERFORMED BECAUSE PATIENT REFUSED THE ECG MEASUREMENT.
			V6 (WEEK 52)	370	06DEC2011	COAGULATION TEST	COAGULATION TEST WAS NOT PERFORMED. IT WAS NOT NECESSARY AS PATIENT REFUSED LUMBAR PUNCTURE.
Placebo	001	1	V1 (WEEK 0)	1	09APR2009	COAGULATION TEST	COAGULATION TEST NOT DONE. VALUES FROM SCREENING VISIT ARE SUFFICIENT FOR LUMBAR PUNCTURE.
	003	1	SCREENING	-21	07MAY2009	SUMMARY OF INCLUSION / EXCLUSION CRITERIA	DATE OF SUMMARY IS 28/05/2009

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	003	1	SCREENING	-21	07MAY2009	QUESTIONNAIRES AND TESTS	PATIENT COULD NOT PERFORM CHOICE REACTION TEST AND TRAIL MAKING TEST.
			V1 (WEEK 0)	1	28MAY2009	VITAL SIGNS / BODY WEIGHT / BODY HEIGHT COAGULATION TEST	CONTROL IN SUPINE POSITION: SBP 130 DBP 080 PR 072 COAGULATION TEST NOT DONE_ VALUES FROM SCREENING VISIT ARE SUFFICIENT FOR LUMBURE PUNCTURE
			V3 (WEEK 12)	90	25AUG2009	QUESTIONNAIRES AND TESTS COAGULATION TEST	MISSING DATA FLUID SAMPLING NOT DONE, PATIENT REFUSED, SO COAGULATION TEST AND NEW MRI (NOT OLDER THAN 4 MONTH) NOT NECESSARY AND NOT DONE
						QUESTIONNAIRES AND TESTS	WECHSLER VERBAL PAIRED ASSOCIATES WAS NOT DONE BECAUSE PATIENT REFUSED TEST
						CEREBROSPINAL FLUID SAMPLING REPORT FROM FORMER MRI ASSESSMENT	SEE PROTOCOL DEVIATION FORM MRI ASSESSMENT WAS NOT PERFORMED AS NO CSF HAS BEEN SAMPLED (PATIENT REFUSED CSF SAMPLING)
			V5 (WEEK 36)	253	04FEB2010	12-LEAD ECG-EVALUATION VITAL SIGNS	ECG NOT DONE DUE TO DROP OUT OF PATIENT DURING V5. VITAL SIGNS WERE NOT TAKEN DURING THAT VISIT DUE TO THE DROP OUT OF THIS PATIENT.

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Placebo	003	1	V5 (WEEK 36)	253	04FEB2010	BLOOD SAMPLING	BLOOD SAMPLING WAS NOT PERFORMED DURING VISIT 5 AS THE PATIENT DROPPED OUT.
						URINE SAMPLING	URINE SAMPLING HAS NOT BEEN PERFORMED DURING VISIT 5 AS THE PATIENT DISCONTINUED PARTICIPATION IN THE TRIAL.
						QUESTIONNAIRES AND TESTS	QUESTIONNAIRES AND TESTS HAVE NOT BEEN PERFORMED DURING VISIT 5 AS THE PATIENT DROPPED OUT.
	005	2	V3 (WEEK 12)	83	25AUG2009	VITAL SIGNS	NOT TAKEN DURING THIS VISIT
			V5 (WEEK 36)	258	16FEB2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	22 TABLETS WERE RETURNED LATER.
	009	1	V1 (WEEK 0)	1	08SEP2009	COAGULATION TEST	COAGULATION TEST NOT DONE BECAUSE VALUES FROM SCREENING VISIT ARE SUFFICIENT.
							VISIT WAS PERFORMED LATER DUE TO PRIVATE REASON OF THE PATIENT. SEE PROTOCOL DEVIATION FORM
			V5 (WEEK 36)	246	11MAY2010	QUESTIONNAIRES AND TESTS	BECAUSE THE PATIENT WAS UNABLE CONTINUE FOR TRAIL MAKING TEST
			V7 (WEEK 56)	389	01OCT2010	QUESTIONNAIRES AND TESTS	ONLY PART A COULD BE PERFORMED . REACTION TEST VISIT 7: MISSING DATA

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Placebo	011	1	SCREENING	-21	05NOV2009	EXCLUSION CRITERIA	THE PATIENT HAS RECEIVED PREVIOUSLY MEMANTINE. WRITTEN CONSENT WAS OBTAINED BY THE SPONSOR AND DOCUMENTED IN A PROTOCOL WAIVER.
			V1 (WEEK 0)	1	26NOV2009	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	SEE COMMENT ON SCREENING VISIT / PROTOCOL WAIVER
			V2 (WEEK 4)	35	30DEC2009	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	SEE COMMENT ON SCREENING / PROTOCOL WAIVER
			V6 (WEEK 52)	366	26NOV2010	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1 AND 2 WERE NOT DONE. TRAIL MAKING TEST A AND B HAD TO BE ABORTED DUE TO EXCESSIVE DEMANDS OF THE PATIENT. A PROTOCOL DEVIATION FORM WAS WRITTEN.
			V7 (WEEK 56)	397	27DEC2010	BLOOD SAMPLING	THE BLOOD SAMPLE (EDTA PLASMA) WAS STORED BY -20 C FROM 27. UNTIL 28.12.2010 DUE TO DRYICE SHIPMENT PROBLEMS BY TNT.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	011	1	V7 (WEEK 56)	397	27DEC2010	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1 AND 2 WERE NOT DONE. TRAIL MAKING TEST A AND B WERE ABORTED DUE TO EXCESSIVE DEMANDS OF THE PATIENT. A PROTOCOL DEVIATION FORM WAS WRITTEN.
						URINE SAMPLING	IN URINE SAMPLING SIGNS FOR AN URINARY TRACT INFECTION, GP WAS INFORMED.
	013	4	SCREENING	-30	17AUG2009	COMMENTS	ECHO-CARDIOGRAPHY AND 24H-ECG ARE SCHEDULED ON 08.09.2009 (BEFORE VISIT 1) MRT IS SCHEDULED ON 27.08.2009
			V1 (WEEK 0)	1	16SEP2009	URINE SAMPLING	NO TEST STIX WERE AVAILABLE ON THE VISIT DAY IN THE STUDY CENTER.
			V3 (WEEK 12)	85	09DEC2009	12-LEAD ECG-EVALUATION	NO CLINICALLY SIGNIFICANT FINDINGS WERE DETECTED. THE INVESTIGATOR ONLY COMMENTED ON RESULTS WHICH WERE OBTAINED ON A PRECEDING VISIT.
	016	4	SCREENING	-28	01FEB2010	REPORT FROM FORMER MRI ASSESSMENT	MRI IS SCHEDULED ON 01.03.2010 ON THE BASELINE-VISIT DATE

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Placebo	016	4	SCREENING	-28	01FEB2010	EXCLUSION CRITERIA	HYPERCHOLESTEROLEMIA WAS BEING TREATED WITH MEDICATION AND MAY THEREFORE BE RATED AS CLINICALLY SIGNIFICANT. NEVERTHELESS, THIS DOES NOT CONSTITUTE A CRITERION FOR EXCLUSION FROM THE STUDY.
						EXCLUSION CRITERIA	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V3 (WEEK 12)	80	19MAY2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	ONE BLISTER HAS BEEN FORGOTTEN TO BE RETURNED AND WILL BE SENT BY POST LATER ON.
						COAGULATION TEST	PATIENT REFUSED LUMBAR PUNCTURE, THEREFORE COAGULATION TEST WAS NOT DONE
	018	5	V1 (WEEK 0)	1	23NOV2009	COAGULATION TEST	BLOOD WAS DRAWN BEFORE LUMBAR PUNCTURE TO HAVE RESULTS IN TIME
	024	4	V3 (WEEK 12)	87	10NOV2010	COMMENTS	PATIENT IS SCHEDULED FOR A CATARACT SURGERY ON 30.11.2010
						COAGULATION TEST	COAGULATION TEST NOT NECESSARY BECAUSE NO CSF SAMPLING WAS PERFORMED.
			V7 (WEEK 56)	393	12SEP2011	QUESTIONNAIRES AND TESTS	NOT AVAILABLE

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	028	20	SCREENING	-8	18NOV2010	RELEVANT MEDICAL & SURGICAL HISTORY (OTHER DISEASES THAN AD)	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V3 (WEEK 12)	89	22FEB2011	COAGULATION TEST	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V5 (WEEK 36)	273	25AUG2011	COMMENTS	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V6 (WEEK 52)	364	24NOV2011	REPORT FROM FORMER MRI ASSESSMENT COMMENTS	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
	029	8	SCREENING	-3	26JAN2010	VITAL SIGNS BLOOD SAMPLING	BODY WEIGHT NOT DONE, PDF WRITTEN NCS, DUE TO UNDERLYING DISEASE
			V3 (WEEK 12)	82	20APR2010	PRIOR/CONCOMITANT MEDICATION/THERAPY COAGULATION TEST	VISIT DATE OUTSIDE TIME WINDOW-PDF WRITTEN NOT DONE BECAUSE NO CSF SAMPLING PERFORMED
						REPORT FROM FORMER MRI ASSESSMENT	NOT DONE BECAUSE NO CSF SAMPLING PERFORMED.
						QUESTIONNAIRES AND TESTS	1 PAGE OF REACTION TIME TEST (BS) COULD NOT BE PRINTED DATA WERE NOT SAVED AND GOT LOST. PDF WAS WRITTEN.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	029	8	V4 (WEEK 24)	158	05JUL2010	COMMENTS	LEUCOCYTES: 7-10 / HPF EPITHELIAL CELLS: 7-10 /HPF ROUND EPITHELIAL CELLS: 3-6 / HPF BACTERIA: MASSIVE / HPF CRYSTALS: POSITIV / HPF ADDITIONAL URINE SAMPLING WAS PERFORMED AS A FURTHER CONTROL. U-LEUCOCYTES: 25/ μ L - CLIN. SIGN. BACTERIA ++ - CLIN. SIGN. CRYSTALS POSITIVE (URIC ACID ++) - CLIN. SIGN.
			V5 (WEEK 36)	245	30SEP2010	BLOOD SAMPLING	ADDITIONAL SIGNIFICANT VALUES: BACTERIA ++ /HPF CRYSTALE: POSITIVE / HPF
						COMMENTS	BATCERIA ++/HPF CRYSTALE POSITIVE/HPF
						URINE SAMPLING	
	031	8	V6 (WEEK 52)	363	17MAY2011	COAGULATION TEST REPORT FROM FORMER MRI ASSESSMENT	PATIENT DENIED PATIENT DENIED
	034	9	SCREENING	-22	24FEB2010	QUESTIONNAIRES AND TESTS	TMT-B AND WECHSLER VERBAL PAIRED ASSOCIATE WERE NOT PERFORMED DUE TO THE PATIENTS DISABILITY

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	034	9	SCREENING	-22	24FEB2010	EXCLUSION CRITERIA	COAGULATION (PTT) WAS ABOVE NORM RANGE ON SCREENING VISIT. HOWEVER TESTS WERE REPEATED ON VISIT 1 (18/MAR/2010) WITH NORMAL VALUES (PTT = 28.3 SEC). PATIENT WAS THEREFORE ENROLLED
						INFORMED CONSENT	NO INFORMED CONSENT FORM FOR THE PHARMACOGENETIC EXAMINATIONS WAS SIGNED BY THE PATIENT BECAUSE THE SITE FORGOT TO HAND THIS FORM OVER TO THE PATIENT. THE PATIENT WAS ASKED TO RE-SIGN THE FORM AT A LATER VISIT. A RESPECTIVE PROTOCOL DEVIATION FORM WAS PREPARED AND SIGNED.
			V1 (WEEK 0)	1	18MAR2010	QUESTIONNAIRES AND TESTS	NTB TEST NOT COMPLETED
						QUESTIONNAIRES AND TESTS	TMT, NTB, CHOICE REACTION TASK 1&2 WERE NOT PERFORMED DUE TO THE PATIENTS DISABILITY
						REPORT FROM FORMER MRI ASSESSMENT	STUDY SITE FORGOT TO PERFORM A MRI. A RESPECTIVE PROTOCOL DEVIATION FORM WAS PREPARED AND SIGNED BY THE INVESTIGATOR.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	034	9	V1 (WEEK 0)	1	18MAR2010	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	COAGULATION (PTT) WAS ABOVE NORM RANGE ON SCREENING VISIT. HOWEVER TESTS WERE REPEATED ON VISIT 1 (18/MAR/2010) WITH NORMAL VALUES (PTT = 28.3 SEC). PATIENT WAS THEREFORE ENROLLED
			V2 (WEEK 4)	27	13APR2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	24 TABLETS WERE RETURNED AT THE NECT VISIT.
			V3 (WEEK 12)	83	08JUN2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY QUESTIONNAIRES AND TESTS 12-LEAD ECG-EVALUATION CEREBROSPINAL FLUID SAMPLING	FOUR EMPTY BLISTERS WERE NOT RETURNED. SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 2 AND TMT-B NOT DONE AT THIS VISIT ECG WAS FORGOTTEN TO PERFORMED VISIT 3 WAS SCHEDULED TO EARLY (TWO DAYS) DUE TO SCHEDULING PROBLEMS WITH THE PATIENT. A RESPECTIVE PROTOCOL DEVIATION FORM WAS PREPARED AND SIGNED. LUMBAR PUNCTURE WAS PERFORMED ONE WEEK LATER THAN THE VISIT DATE. A RESPECTIVE PROTOCOL DEVIATION FORM WAS CREATED AND SIGNED.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	034	9	V3 (WEEK 12)	83	08JUN2010	12-LEAD ECG-EVALUATION	TO DOCUMENT THE MISSING ECG A RESPECTIVE PROTOCOL DEVIATION FORM WAS CREATED AND SIGNED.
			V4 (WEEK 24)	175	08SEP2010	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1&2 AND TMT-B WERE NOT PERFORMED.
			V5 (WEEK 36)	258	30NOV2010	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1&2 AND TMT-B WERE NOT PERFORMED.
			V6 (WEEK 52)	363	15MAR2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY URINE SAMPLING	TWO EMPTY BLISTERS WERE NOT RETURNED TO THE SITE. ACCORDING TO DIARY PATIENT SHOULD HAVE RETURNED 70 TABLETS URINE COULD NOT BE COLLECTED BECAUSE PATIENT DID NOT HIT THE BEAKER
						QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST,CHOICE REACTIONS TASK AND TRAIL MAKING TEST WERE NOT PERFORMED
			V7 (WEEK 56)	399	20APR2011	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST,CHOICE REACTIONS TASK AND TRAIL MAKING TEST PART B WERE NOT PERFORMED

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	041	12	SCREENING	-16	23SEP2009	SUMMARY OF INCLUSION / EXCLUSION CRITERIA	SIGNATURE DATE UPDATED AFTER CHANGES TO CRF. THE COMPLIANCE OF INCLUSION AND EXCLUSION CRITERIA WERE VERIFIED BEFORE VISIT 1 ON OCT., 9TH 2009
						RELEVANT MEDICAL & SURGICAL HISTORY (OTHER DISEASES THAN AD)	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION
			V5 (WEEK 36)	251	16JUN2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	TWO BLISTERS WERE THROWN AWAY BY PATIENT
	044	12	SCREENING	-28	04NOV2009	REPORT FROM FORMER MRI ASSESSMENT VITAL SIGNS REPORT FROM FORMER MRI ASSESSMENT	MRI WAS ORDERED BECAUSE ELSE NOT AVAILABLE AT SCREENING BODY WEIGHT WAS NOT MEASURED AT VS MRI WAS PERFORMED FOR STUDY REASONS ONE DAY BEFORE SCREENING VISIT
			V2 (WEEK 4)	37	07JAN2010	PRIOR/CONCOMITANT MEDICATION/THERAPY	VISIT 2 WAS PERFORMED 3 DAYS OUT OF RANGE BECAUSE PATIENT WAS NOT ABLE TO COME IN TIME
			V4 (WEEK 24)	176	26MAY2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	9 BLISTERS WERE THROWN AWAY BY PATIENT
			V5 (WEEK 36)	260	18AUG2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	3 BLISTERS WERE THROWN AWAY BY PATIENT

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	044	12	V6 (WEEK 52)	365	01DEC2010	REPORT FROM FORMER MRI ASSESSMENT	MRT FAILED BECAUSE PATIENT WAS TOO AGITATED.
	045	11	SCREENING	-14	07DEC2009	INFORMED CONSENT	INITIALLY, THE SITE FORGOT TO INVOLVE AN INDEPENDENT PHYSICIAN IN THE INFORMED CONSENT PROCESS. DR. GUIDO STRATEN WAS ASKED TO ACT AS AN INDEPENDENT PHYSICIAN FOR THIS STUDY WHO LATER MET THE PATIENT AND SIGNED THE NEW VERSION 5.0 OF THE INFORMED CONSENT FORM. A PROTOCOL DEVIATION FORM FOR THIS ISSUE WAS CREATED AND SIGNED. DURING THE SCREENING VISIT LAB RESULTS FOR PTT WERE INCREASED. PTT WAS RE-CHECKED AT VISIT 1 AND WAS OK. THEREFORE PATIENT WAS ENROLLED ALTHOUGH THE INCREASED PTT VALUES AT THE SCREENING VISIT. A PROTOCOL DEVIATION FORM FOR THIS ISSUE WAS CREATED AND SIGNED.

EXCLUSION CRITERIA

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	045	11	V1 (WEEK 0)	1	21DEC2009	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	PATIENT WAS ENROLLED DESPITE INCREASED PTT IN BASELINE BECAUSE HE SHOWED NORMAL PTT AT VISIT 1. THE PTT VALUES AT BASLINE VISIT WERE CONSIDERED NOT CLINICAL SIGNIFICANT.
						ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	DURING THE SCREENING VISIT LAB RESULTS FOR PTT WERE INCREASED. PTT WAS RE-CHECKED AT VISIT 1 AND WAS OK. THEREFORE PATIENT WAS ENROLLED ALTHOUGH THE INCREASED PTT VALUES AT THE SCREENING VISIT. A PROTOCOL DEVIATION FORM FOR THIS ISSUE WAS CREATED AND SIGNED.
			V3 (WEEK 12)	85	15MAR2010	COAGULATION TEST	NOT NECESSARY BECAUSE NO LUMBAR PUNCTURE HAS BEEN PERFORMED
	047	11	SCREENING	-21	12JUL2010	QUESTIONNAIRES AND TESTS	WECHSLER VERBAL PAIRED ASSOCIATES WAS NOT PERFORMED BECAUSE PATIENT REFUSED.
			V1 (WEEK 0)	1	02AUG2010	QUESTIONNAIRES AND TESTS	WECHSLER VERBAL PAIRED ASSOCIATES WAS NOT PERFORMED BECAUSE PATIENT REFUSED.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	047	11	V3 (WEEK 12)	80	20OCT2010	COAGULATION TEST	COAGULATION TEST WAS NOT PERFORMED BECAUSE NO LUMBAR PUNCTURE WAS DONE.
						QUESTIONNAIRES AND TESTS	PATIENT REFUSED WECHSLER VERBAL PAIRED ASSOCIATES
						CEREBROSPINAL FLUID SAMPLING	PAT. DID NOT WANT LP. DATE HAS BEEN DELETED
			V4 (WEEK 24)	162	10JAN2011	QUESTIONNAIRES AND TESTS	PATIENT REFUSED WECHSLER VERBAL PAIRED ASSOCIATES
			V6 (WEEK 52)	360	27JUL2011	QUESTIONNAIRES AND TESTS	WECHSLER VERBAL PAIRED ASSOCIATES TEST WAS NOT DONE BECAUSE PATIENT DID NOT UNDERSTAND INSTRUCTIONS.
			V7 (WEEK 56)	393	29AUG2011	QUESTIONNAIRES AND TESTS	WECHSLER VERBAL PAIRED ASSOCIATES TEST WAS NOT DONE BECAUSE PATIENT DID NOT UNDERSTAND INSTRUCTIONS.
	049	21	UNSCHEDULED	213	27MAY2011	VITAL SIGNS	WAS NOT MEASURED
			V1 (WEEK 0)	1	27OCT2010	CEREBROSPINAL FLUID SAMPLING	URIN PROTEIN VALUES HAS BEEN NORMAL AT UNSCHEDULED VISIT.
			V4 (WEEK 24)	168	12APR2011	URINE SAMPLING	PATIENT SIGNED HOSPITAL'S VERSION OF THE ICF FOR LUMBAR PUNCTURE. THE PATIENT WILL SIGN THE ICF (LUMBAR PUNCTURE) OF THE CASE REPORT FORM AT HIS NEXT VISIT.
							PATIENT IS POSTMENOPAUSAL

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	051	21	V1 (WEEK 0)	1	28OCT2010	CEREBROSPINAL FLUID SAMPLING	PATIENT SIGNED HOSPITAL'S VERSION OF THE ICF FOR LUMBAR PUNCTURE. THE PATIENT WILL SIGN THE ICF (LUMBAR PUNCTURE) OF THE CASE REPORT FORM AT HIS NEXT VISIT.
			V6 (WEEK 52)	363	25OCT2011	REPORT FROM FORMER MRI ASSESSMENT	MRI WAS DONE AFTER LP, A PROTOCOL DEVIATION FORM WILL BE FILLED OUT AND FILED WITHIN THE ISF.
	056	5	V6 (WEEK 52)	364	19APR2011	REPORT FROM FORMER MRI ASSESSMENT	DUE TO PATIENT ORGANIZATION THE MRI COULD NOT BE OBTAINED AHEAD OF LUMBAR PUNCTURE. IN THE OPINION OF THE INVESTIGATOR THIS WAS NOT AT RISK FOR THE PATIENT.
			V7 (WEEK 56)	393	18MAY2011	QUESTIONNAIRES AND TESTS QUESTIONNAIRES AND TESTS	NOT AVAILABLE NOT AVAILABLE
	058	1	SCREENING	-21	06DEC2010	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1 AND 2 AND WECHSLER VERBAL PAIRED ASSOCIATES WERE NOT DONE. PATIENT REFUSED THE TESTS. A PROTOCOL DEVIATION FORM WAS WRITTEN.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	058	1	V1 (WEEK 0)	1	27DEC2010	COAGULATION TEST	COAGULATION TEST WAS NOT DONE AS VALUES FROM SCREENING VISIT ARE SUFFICIENT FOR LP.
						QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK 1 AND 2 AND WECHSLER VERBAL PAIRED ASSOCIATES WERE NOT DONE. PATIENT REFUSED THE TESTS. A PROTOCOL DEVIATION FORM WAS WRITTEN.
			V3 (WEEK 12)	93	29MAR2011	COAGULATION TEST	BECAUSE PATIENT REFUSED CSF SAMPLING NO COAGULATION TEST AND MRI WERE NECESSARY.
						REPORT FROM FORMER MRI ASSESSMENT	BECAUSE PATIENT REFUSED CSF SAMPLING NO COAGULATION TEST AND MRI WERE NECESSARY.
						QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
						DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	AFTER VISIT 3 PATIENT LOST 2 PACKS OF MEDICATION, SO HE HAS GOT 2 PACKS OF VISIT 4 MEDICATION.
			V4 (WEEK 24)	166	10JUN2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	THE LOST TWO PACKS OF TABLETS (2X 70) FROM VISIT 3 WERE FOUND AND RETURNED ON VISIT 4.

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Placebo	058	1	V4 (WEEK 24)	166	10JUN2011	QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
						12-LEAD ECG-EVALUATION	ECG WAS PERFORMED BUT COULD NOT BE RECORDED. THEREFORE NO ASSESSMENT AVAILABLE. A PROTOCOL DEVIATION FORM WAS WRITTEN.
			V5 (WEEK 36)	260	12SEP2011	QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
						12-LEAD ECG-EVALUATION	ECG WAS PERFORMED BUT COULD NOT BE RECORDED. THEREFORE NO ASSESSMENT AVAILABLE. A PROTOCOL DEVIATION FORM WAS WRITTEN.
			V6 (WEEK 52)	345	06DEC2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	THE CSF SAMPLING COULD NOT BEEN PERFORMED BEFORE 13-DEC-2011 THEREFORE THE INTAKE OF MEDICATION DID NOT STOP BEFORE 13-DEC-2011. PDF HAS BEEN WRITTEN.
						CONCOMITANT MEDICATION / THERAPY	
						COAGULATION TEST	FLUID SAMPLING HAS BEEN PERFORMED ONE WEEK LATER (06-DEC-2011).
						QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.

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Placebo	058	1	V7 (WEEK 56)	380	10JAN2012	CONCOMITANT MEDICATION / THERAPY QUESTIONNAIRES AND TESTS	A PDF HAS BEEN CREATED. COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
	059	1	SCREENING	-2	27DEC2010	QUESTIONNAIRES AND TESTS	SIMPLE REACTION TIME TEST, CHOICE REACTION TASK WERE NOT DONE. PATIENT REFUSED THE TESTS. A PROTOCOL DEVIATION FORM WAS WRITTEN.
			V1 (WEEK 0)	1	29DEC2010	COAGULATION TEST URINE SAMPLING QUESTIONNAIRES AND TESTS	COALUGATION TEST HAS NOT BEEN PERFORMED AS VALUES FROM SCREENING VISIT ARE SUFFICIENT FOR LP. A CONTROL WAS PERFORMED ONSITE AT VISIT 2. NO SIGNS FOR ELEVATED GLUOSEVALUES IN URINE. SIMPLE REACTION TIME TEST, CHOICE REACTION TASK WERE NOT DONE. PATIENT REFUSED THE TESTS. A PROTOCOL DEVIATION FORM WAS WRITTEN.

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Placebo	059	1	V3 (WEEK 12)	93	31MAR2011	COAGULATION TEST	BECAUSE PATIENT REFUSED CEREBROSPINAL FLUID SAMPLING, AN ACTUAL MRI AND A COAGULATION TEST WERE NOT NECESSARY.
						REPORT FROM FORMER MRI ASSESSMENT	BECAUSE PATIENT REFUSED CEREBROSPINAL FLUID SAMPLING, AN ACTUAL MRI AND A COAGULATION TEST WERE NOT NECESSARY.
						BLOOD SAMPLING	A LABORATORY KIT OF VISIT 5 WAS TAKEN BY MISTAKE. THEREFORE THE SAMPLE FOR DETERMINATION OF ACI-91 IS MISSING. SEE PROTOCOL DEVIATION FORM.
						QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
			V4 (WEEK 24)	161	07JUN2011	QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
						12-LEAD ECG-EVALUATION	DUE TO TECHNICAL REASONS THE ECG HAS NOT BEEN RECORDED. A PDF HAS BEEN WRITTEN.
			V5 (WEEK 36)	254	08SEP2011	QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.

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Placebo	059	1	V6 (WEEK 52)	345	08DEC2011	QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
			V7 (WEEK 56)	380	12JAN2012	QUESTIONNAIRES AND TESTS	COMPUTERIZED TEST WAS NOT PERFORMED BECAUSE PATIENT REFUSED THE TEST.
	065	16	SCREENING	-20	10AUG2010	QUESTIONNAIRES AND TESTS	WECHSLER VERBAL PAIRED ASSOCIATES - TEST WAS COMPLETED BECAUSE THE PATIENT REFUSED TO CONTINUE. ALCOHOL DEPENDENCE WAS NOT KNOWN AT TIME OF SCREENING
			V1 (WEEK 0)	1	30AUG2010	COAGULATION TEST QUESTIONNAIRES AND TESTS	COAGULATION TEST NOT PERFORMED BECAUSE RESULTS IN NORMAL RANGE AT SCREENING VISIT AND SUFFICIENT. WECHSLER VERBAL PAIRED ASSOCIATES AND TRAIL MAKING TEST WERE INCOMPLETE BECAUSE THE PATIENT WAS UNABLE TO COMPLETE THE TESTS.

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Placebo	065	16	V2 (WEEK 4)	29	27SEP2010	COMMENTS	PATIENT: FEELS QUEERISH, FORGETS WHAT HE MEANT TO SAY. NO CHANGE IN CONCOMITANT MEDICATION. THE MOOD IS AFFECTED BY WEATHER SINCE TWO DAYS, CAREGIVER: -NO CHANGES
			V3 (WEEK 12)	85	22NOV2010	COMMENTS	NURSING SERVICE CHECKED THE INTAKE OF THE STUDY MEDICATION CAREGIVER: PATIENT PERMANENTLY IN CARE. PROFESSIONAL CAREGIVER IS INFORMED ABOUT THE STUDY. PATIENT: GOOD TOLERABILITY OF STUDY MEDICATION FEELING OF WARMTH IN HEAD AND UPPER PART OF BODY.
			V4 (WEEK 24)	141	17JAN2011	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	PATIENT DESTROYED BY MISTAKE STUDY MEDICATION AND DIARY

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	065	16	V4 (WEEK 24)	141	17JAN2011	COMMENTS	PATIENT: PAIN IN BOTH LEGS. NO CHANGE IN MEMORY, FEELING GOOD. CAREGIVER: LOSS OF MEMORY IS WORSENING, ALSO WORSENING LOSS OF SPEECH (HE CANT SPEAK COMPLETE SENTENCES ANYMORE) PATIENT FEELING STALKED, PERMANENTLY CHANGING OF MOOD FROM FEELING GOOD TO FEELING STALKED. LOSS OF TIME ORIENTATION (DATE)
	068	16	V1 (WEEK 0)	1	22NOV2010	COAGULATION TEST	COAGULATION AT SCREENINGVISIT WAS NCS, THEREFORE NO NEW TEST WAS NESSESSARY
			V3 (WEEK 12)	81	10FEB2011	COMMENTS DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	FORGETFULNESS INCREASES PATIENT DISCARDED EMPTY PACKAGE WITH 7 EMPTY BLISTERS BY MISTAKE
			V5 (WEEK 36)	262	10AUG2011	COMMENTS	PATIENT INFORMATION VERSION 6 PROVIDED TO PATIENT AT 20-09-2011.
			V6 (WEEK 52)	372	28NOV2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY COMMENTS	PATIENT RETURNED 62 TABLET AT VISIT 7 TELEFONCALL 13-10-2011: PATEINT FEEL STABIL, PARTNER SUFFERS UNDER HIS INCONTINENCIA. PATIENT SLEEP ALLOT

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	068	16	V7 (WEEK 56)	414	09JAN2012	COMMENTS	BOWEL CT PLANNED BECAUSE OF LOSS OF WEIGHT DRUGACCOUNTABILITY OF V5-> V6= 62 TABLETS PATIENT BROUGHT MEDICATION AND DIARY ON VISIT 7. VISIT 7 DELAYED. PATIENT FORGOT APPOINTMENT AND WASNT AVAILABLE BEVOR THAT DATE. LAST INTAKE OF STUDY MEDICATION ACCORDING TO DIARY ON 11-12-2012. THIS IS NOT VALID ACCORDING TO CAREGIVER.
						QUESTIONNAIRES AND TESTS	DATA LOST!
	069	23	V1 (WEEK 0)	1	07DEC2010	12-LEAD ECG-EVALUATION	ECG NOT DONE AT VISIT 1
			V7 (WEEK 56)	401	11JAN2012	COMMENTS	INVESTIGATOR NOT AVAILABLE FOR CONFIRMATION.
	072	18	SCREENING	-20	01DEC2010	EXCLUSION CRITERIA	PTT MEASUREMENT WAS CONTROLLED AND WAS NORMAL BEFORE LUMBAR PUNCTURE AND INCLUSION.
			V2 (WEEK 4)	31	20JAN2011	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	PATIENT DID NOT RETURN 5 EMPTY BLISTERS.
						DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	1 EMPTY BLISTER OF THE 5 MISSING ONES WAS RETURNED BY THE PATIENT AT VISIT 3 (15/03/2011).

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	072	18	V3 (WEEK 12)	85	15MAR2011	COAGULATION TEST	AS NO LUMBAR PUNCTURE WAS PERFORMED AT VISIT 3 (OPTIONAL AT VISIT 3) NO COAGULATION TEST AND MRI ASSESSMENT NECESSARY.
			V6 (WEEK 52)	360	15DEC2011	DISPENSING OF PATIENT DIARY REPORT FROM FORMER MRI ASSESSMENT	PATIENT DIARY OF V6 DISPENSED AGAIN FOR FILLING IN EVENTUAL AES. MRI ASSESSMENT WAS PERFORMED ON 13/12/2011.
	079	13	SCREENING	-18	19JUL2010	EXCLUSION CRITERIA	AFTER DISCUSSION WITH THE SPONSOR PATIENT WAS ALLOWED TO ENROLL.
			V1 (WEEK 0)	1	06AUG2010	COMMENTS COMMENTS	COAGULATION WAS REPEATED ON 12-AUG-2010 (115% QUICK, PPT 30,7SEC., INR 0,92) VISIT WAS DONE ON 2 DAYS, FIRST DAY ALL TESTS WERE DONE AND ON THE 2. DAY THE CSF AND RANDOM OF THE PATIENT WAS DONE, THE REASON WAS THE MISSING MRT ON THE 6-AUG-2010

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	079	13	V1 (WEEK 0)	1	06AUG2010	12-LEAD ECG-EVALUATION	VISIT 1 HAD TO BE SPLIT INTO TWO DAYS SINCE THE SITE RECOGNIZED ON 06/08/2010 THAT NO ACTUAL MRI WAS AVAILABLE. ALL LABORATORY PROCEDURES AS WELL AS THE ECG WAS PERFORMED ON 06/08/2010. THE MRI, LUMBAR PUNCTURE AND AN ADDITIONAL COAGULATION TEST AS WELL AS THE RANDOMIZATION OF THE PATIENT WAS PERFORMED ON 12/08/2010.
			V3 (WEEK 12)	96	09NOV2010	QUESTIONNAIRES AND TESTS	TESTS WERE PERFORMED 7 DAYS LATER (16.11.2010) THAN ACTUAL VISIT DUE TO DELAYED ARRIVAL AT THE CLINIC.
	082	17	V1 (WEEK 0)	1	14OCT2010	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	CAREGIVER LOST DIARY, A COPY WAS MADE.
	084	17	V2 (WEEK 4)	29	15DEC2010	DRUG ACCOUNTABILITY AND REVIEW OF PATIENT DIARY	EMPTY BLISTER WERE THROWN AWAY BY CAREGIVER.

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	084	17	V2 (WEEK 4)	29	15DEC2010	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	2 PACKS FROM VISIT 3 WERE HANDED OVER TO THE PATIENT BY MISTAKE.
			V3 (WEEK 12)	84	08FEB2011	ELIGIBILITY OF PATIENT / RANDOMIZATION / DISPENSING OF STUDY MEDICATION AND PATIENT DIARY	THE 2 PACKS FROM VISIT 2 WERE HANDED OVER TO THE PATIENT.
			V6 (WEEK 52)	371	22NOV2011	BLOOD SAMPLING	SAMPLE TUBE WAS COAGULATED, THEREFORE NO RESULT AVAILABLE.
			V7 (WEEK 56)	394	15DEC2011	BLOOD SAMPLING	BLOOD SAMPLING FOR HEMATOLOGY WAS NOT PERFORMED BY MISTAKE.
	086	21	SCREENING	-24	04OCT2010	RELEVANT MEDICAL & SURGICAL HISTORY (OTHER DISEASES THAN AD)	START DATE IS UNKNOWN (ENTRY UNK.UNK.UNK IS NOT POSSIBLE)
			V1 (WEEK 0)	1	28OCT2010	CEREBROSPINAL FLUID SAMPLING	PATIENT SIGNED HOSPITAL'S VERSION OF THE ICF FOR LUMBAR PUNCTURE. THE PATIENT WILL SIGN THE ICF (LUMBAR PUNCTURE) OF THE CASE REPORT FORM AT HIS NEXT VISIT.
			V6 (WEEK 52)	363	25OCT2011	URINE SAMPLING	PREGNANCY TEST WAS NOT DONE BECAUSE PATIENT IS POSTMENOPAUSAL
						REPORT FROM FORMER MRI ASSESSMENT	COMMENT AVAILABLE IN SECTION 'COMMENTS' AT THE END OF THE VISIT

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	088	16	V1 (WEEK 0)	1	09DEC2010	COAGULATION TEST	DUE TO COAGULATIONPARAMETER ON SCREENING VISIT WAS NORMAL PATIENT: FEELING BETTER, OCCASIONALLY PAIN IN CERVICAL SPINE. FEELING BALANCED. HELPS HER CHLIDREN IN THEIR SHOP. CAREGIVER: WAS VERY IRRITATED ESPECIALLY SINCE 3 WEEKS. WORSENING OF MEMORY, ADDICTED TO SWEETS. TAKES SWEETS FROM THE SHELF DURING SHOPPING. STRONG UP AND DOWN. SUBJECTIVE WELLBEING, BACKPAIN DUE TO CERVICAL SPINE. CAREGIVER WAS IN HOSPITAL, PATIENT STAID BY THE CHILDREN. IN THIS TIME, PATIENT WAS IRRITATED, THEREFORE 2,5 ML EUNERPAN. NO CHANGE IN RISPERIDON, ONE TABLET FORGOTTEN. PATIENT REFUSED CONTINUATION OF NTB.
			V2 (WEEK 4)	27	04JAN2011	COMMENTS	
			V4 (WEEK 24)	162	19MAY2011	COMMENTS	
			V5 (WEEK 36)	264	29AUG2011	QUESTIONNAIRES AND TESTS	

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Treat- ment	Random No.	Site ID	Visit	Actual day	Visit date	CRF Module	Comment
Placebo	088	16	V5 (WEEK 36)	264	29AUG2011	COMMENTS	WORSENING OF EXALTATION, EMBARRASSMENT IN THE PUBLIC. SAE PROGRESSION OF AD -> 26.07.-23.08.11 -> FAX TO SPONSOR 29.08.11 (WE ARE INFORMED ABOUT SAE AT VISIT 5)
			V6 (WEEK 52)	376	19DEC2011	12-LEAD ECG-EVALUATION COMMENTS	ECG NOT DONE DUE TO PATIENT'S RESTLESSNESS NO MORE AGGRESSION BUT RESTLESSNESS, TONIC PERSEVERATION AND SINGING LOST OF MEMORY IN LAST MONTHS AS PER CAREGIVERS INFORMATIONS SECOND PART OF DIARY NOT RETURNED.
			V7 (WEEK 56)	404	16JAN2012	COMMENTS	CONTINUED WORSENING OF DEMENTIA, AS PER CARGIVER. WORSENING OF RESTLESSNESS, NO MORE AGGRESSIV. SUBSEQUENT PROCESSING BY NEUROLOGIC PRACTITIONER.

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	23APR2009			YES	18:55	
			24APR2009	YES	8:30	YES	18:45	Starke Kopfschmerzen
			25APR2009	YES	7:45	YES	19:15	Versehentlich zum Essen eingenommen
								Kopfschmerzen/Verspannungsschm.
			26APR2009	YES	7:30	YES	18:00	Starke Kopfschmerzen ab ca. 19 Uhr
			27APR2009	YES	7:05	YES	18:30	Starke Kopfschmerzen im oberen Nackenbereich
			28APR2009	YES	7:05	YES	19:00	In der Früh Kopfschmerzen im Stirnbereich
			29APR2009	YES	6:40	YES	19:05	
			30APR2009	YES	7:15	YES	19:00	
			01MAY2009	YES	7:35	YES	19:15	
			02MAY2009	YES	7:40	YES	18:04	
			03MAY2009	YES	9:50	YES	19:00	
			04MAY2009	YES	6:40	YES	18:30	
			05MAY2009	YES	7:00	YES	19:00	22:30 Durchfall
			06MAY2009	YES	7:15	YES	19:15	
			07MAY2009	YES	6:30	YES	19:30	Nachts Durchfall
			08MAY2009	YES	6:40	YES	19:25	Nachts Durchfall
			09MAY2009	YES	7:10	YES	18:30	
			10MAY2009	YES	8:20	YES	18:40	Nachts Durchfall
			11MAY2009	YES	6:30	YES	19:00	
			12MAY2009	YES	7:00	YES	18:55	
			13MAY2009	YES	7:10	YES	18:35	
			14MAY2009	YES	6:30	YES	18:00	
			15MAY2009	YES	7:20	YES	20:00	
			16MAY2009	YES	8:50	YES	18:20	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	17MAY2009	YES	8:15	YES	19:00	
			18MAY2009	YES	6:50	YES	18:19	
			19MAY2009	YES	7:24	YES	20:00	
			20MAY2009	YES	6:30			
			20MAY2009			YES	18:53	
			21MAY2009	YES	9:04	YES	18:12	
			22MAY2009	YES	7:30	YES	22:30	Nach d. Essen abends
			23MAY2009	YES	7:10	YES	19:10	
			24MAY2009	YES	9:30	YES	18:24	
			25MAY2009	YES	6:42	YES	18:25	
			26MAY2009	YES	6:41	YES	20:05	½ Std. nach d. Essen abends
			27MAY2009	YES	6:27	YES	18:00	
			28MAY2009	YES	6:30	YES	18:55	
			29MAY2009	YES	7:00	YES	19:00	
			30MAY2009	YES	7:35	YES	15:30	
			31MAY2009	YES	8:10	YES	19:30	
			01JUN2009	YES	8:40	YES	18:40	
			02JUN2009	YES	7:10	YES	18:45	
			03JUN2009	YES	7:10	YES	18:04	
			04JUN2009	YES	7:05	YES	17:52	
			05JUN2009	YES	8:10	YES	19:41	
			06JUN2009	YES	8:01	YES	16:05	
			07JUN2009	YES	9:53	YES	18:04	
			08JUN2009	YES	6:59	YES	18:10	
			09JUN2009	YES	7:15	YES	18:55	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	10JUN2009	YES	7:15	YES	18:30	
			11JUN2009	YES	8:15		18:00	
			12JUN2009	YES	7:53	YES	18:36	
			13JUN2009	YES	8:04	YES	20:22	
			14JUN2009	YES	9:15	YES	17:40	
			15JUN2009	YES	6:53	YES	17:53	
			16JUN2009	YES	7:10	YES	17:15	
			17JUN2009	YES	8:24	YES	17:30	
			18JUN2009	YES	7:10	YES	17:30	
			19JUN2009	YES	7:00	YES	18:30	
			20JUN2009	YES	7:50	YES	18:18	
			21JUN2009	YES	7:50	YES	17:30	
			22JUN2009	YES	6:20	YES	18:30	
			23JUN2009	YES	7:00	YES	18:40	
			24JUN2009	YES	7:10	YES	16:30	
			25JUN2009	YES	7:10	YES	18:20	
			26JUN2009	YES	8:10	YES	23:15	Wahrscheinlich abends versehentlich 2x. 1. Gabe ca. 18:30.
			27JUN2009	YES	7:15	YES	18:00	
			28JUN2009	YES	8:00	YES	18:00	
			29JUN2009	YES	6:30	YES	18:50	
			30JUN2009	YES	6:55	YES	17:50	
			01JUL2009	YES	6:40	YES	18:00	
			02JUL2009	YES	6:40	YES	17:45	
			03JUL2009	YES	6:50	YES	19:20	

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ACI-91	002	1	04JUL2009	YES	7:15	YES	17:50	
			05JUL2009	YES	7:10	YES	17:40	
			06JUL2009	YES	6:40	YES	18:00	
			07JUL2009	YES	7:15	YES	17:20	
			08JUL2009	YES	7:25			Abends vergessen
			09JUL2009	YES	7:05	YES	17:30	
			10JUL2009	YES	7:35	YES	17:30	
			11JUL2009	YES	7:40	YES	18:00	
			12JUL2009	YES	8:25	YES	18:40	
			13JUL2009	YES	7:20	YES	18:10	
			14JUL2009	YES	6:20	YES	18:30	
			15JUL2009	YES	7:10	YES	17:55	
			16JUL2009	YES	5:45	YES	18:20	
			17JUL2009	YES	7:10	YES	18:15	
			18JUL2009	YES	8:40	YES	17:15	
			19JUL2009	YES	6:00	YES	21:00	
			20JUL2009	YES	6:55	YES	17:45	
			21JUL2009	YES	7:10	YES	17:40	
			22JUL2009	YES	7:40	YES	17:30	
			23JUL2009	YES	6:55	YES	18:00	
			24JUL2009	YES	7:45	YES	17:25	
			25JUL2009	YES	7:05	YES	18:30	
			26JUL2009	YES	8:40	YES	17:00	
			27JUL2009	YES	7:10	YES	16:00	
			28JUL2009	YES	7:40	YES	16:40	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	29JUL2009	YES	6:50	YES	18:05	
			30JUL2009	YES	6:50	YES	17:30	
			31JUL2009	YES	7:35	YES	17:00	
			01AUG2009	YES	7:00	YES	17:05	
			02AUG2009	YES	7:50	YES	18:30	
			03AUG2009	YES	6:35	YES	17:05	
			04AUG2009	YES	6:30	YES	18:05	
			05AUG2009	YES	6:45	YES	18:00	
			06AUG2009	YES	7:00	YES	17:45	
			07AUG2009	YES	6:30	YES	18:35	
			08AUG2009	YES	7:00	YES	20:10	
			09AUG2009	YES	7:50	YES	20:00	
			10AUG2009	YES	6:25	YES	18:15	
			11AUG2009	YES	7:30	YES	17:00	
			12AUG2009	YES	8:15	YES	18:50	
			13AUG2009	YES	9:00	YES	17:30	
			14AUG2009	YES	8:45	YES	17:35	
			15AUG2009	YES	8:30	YES	17:30	
			16AUG2009	YES	8:00	YES	17:40	
			17AUG2009	YES	6:35	YES	18:15	
			18AUG2009	YES	7:25	YES	20:00	
			19AUG2009	YES	7:00	YES	19:30	
			20AUG2009	YES	8:15	YES	19:25	
			21AUG2009	YES	7:55	YES	18:30	
			22AUG2009	YES	9:10	YES	19:15	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	23AUG2009	YES	7:15	YES	20:00	
			24AUG2009	YES	7:25	YES	18:50	
			25AUG2009	YES	7:25	YES	17:30	
			26AUG2009	YES	7:20	YES	17:35	
			27AUG2009	YES	9:15	YES	18:00	
			28AUG2009	YES	9:15	YES	18:05	
			29AUG2009	YES	8:25	YES	18:05	
			30AUG2009	YES	9:25	YES	18:10	
			31AUG2009	YES	7:00	YES	17:55	
			01SEP2009	YES	7:00	YES	17:55	
			02SEP2009	YES	8:00	YES	17:50	
			03SEP2009	YES	7:00	YES	18:40	
			04SEP2009	YES	8:15	YES	20:10	
			05SEP2009	YES	8:15	YES	18:45	
			06SEP2009	YES	7:35	YES	18:05	
			07SEP2009	YES	7:35	YES	18:00	
			08SEP2009	YES	7:40	YES	20:00	
			09SEP2009	YES	7:20	YES	19:30	
			10SEP2009	YES	7:05	YES	19:25	
			11SEP2009	YES	7:30	YES	17:50	
			12SEP2009	YES	8:35	YES	17:45	
			13SEP2009	YES	10:00	YES	17:30	
			14SEP2009	YES	7:15	YES	18:15	
			15SEP2009	YES	7:10	YES	17:45	
			16SEP2009	YES	8:00	YES	17:20	

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ACI-91	002	1	17SEP2009	YES	7:10	YES	18:00	
			18SEP2009	YES	8:10	YES	19:00	
			19SEP2009	YES	9:00	YES	19:30	
			20SEP2009	YES	8:50	YES	18:15	
			21SEP2009	YES	7:35	YES	17:40	
			22SEP2009	YES	7:15	YES	17:30	
			23SEP2009	YES	7:50	YES	17:50	
			24SEP2009	YES	7:15	YES	17:20	
			25SEP2009	YES	7:45	YES	17:10	
			26SEP2009	YES	8:15	YES	20:21	
			27SEP2009	YES	8:30	YES	18:55	
			28SEP2009	YES	6:40	YES	18:35	
			29SEP2009	YES	7:10	YES	19:20	Tbl. kurz vor Essen eingenommen
			30SEP2009	YES	7:05	YES	18:10	
			01OCT2009	YES	7:00	YES	19:00	
			02OCT2009	YES	7:15	YES	18:25	
			03OCT2009	YES	8:25	YES	18:10	
			04OCT2009	YES	9:10	YES	17:30	
			05OCT2009	YES	7:20	YES	18:25	
			06OCT2009	YES	7:15	YES	18:40	
			07OCT2009	YES	7:00	YES	17:45	
			08OCT2009	YES	7:15	YES	18:45	
			09OCT2009	YES	7:20	YES	19:15	
			10OCT2009	YES	8:35	YES	22:10	nach d. Essen eingenommen
			11OCT2009	YES	9:35	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	12OCT2009	YES	7:30	YES	18:15	
			13OCT2009	YES	7:40	YES	19:10	
			14OCT2009	YES	7:10	YES	17:45	
			15OCT2009	YES	7:45	YES	17:30	
			16OCT2009	YES	7:05	YES	18:00	
			17OCT2009	YES	9:00	YES	18:25	
			18OCT2009	YES	9:30	YES	18:05	
			19OCT2009	YES	7:00	YES	18:05	
			20OCT2009	YES	7:10	YES	18:00	
			21OCT2009	YES	7:35	YES	18:45	
			22OCT2009	YES	8:44	YES	18:25	
			23OCT2009	YES	7:15	YES	18:25	
			24OCT2009	YES	8:50	YES	18:30	
			25OCT2009	YES	9:35	YES	17:55	
			26OCT2009	YES	7:10	YES	19:00	
			27OCT2009	YES	7:20	YES	18:05	
			28OCT2009	YES	7:10	YES	17:30	
			29OCT2009	YES	7:15	YES	18:10	
			30OCT2009	YES	7:25	YES	18:00	
			31OCT2009	YES	9:05	YES	17:30	
			01NOV2009	YES	7:50	YES	17:55	
			02NOV2009	YES	7:10	YES	17:20	
			03NOV2009	YES	7:50	YES	17:45	
			04NOV2009	YES	7:10	YES	17:40	
			05NOV2009	YES	7:50	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	06NOV2009	YES	7:55	YES	17:20	
			07NOV2009	YES	8:25	YES	17:30	
			08NOV2009	YES	8:55	YES	17:35	
			09NOV2009	YES	7:15	YES	18:40	
			10NOV2009	YES	7:20	YES	17:45	
			11NOV2009	YES	7:15	YES	18:26	
			12NOV2009	YES	7:15	YES	18:00	
			13NOV2009	YES	7:40	YES	17:55	
			14NOV2009	YES	8:45			abends vergessen
			15NOV2009	YES	9:25	YES	17:30	
			16NOV2009	YES	7:10	YES	17:10	
			17NOV2009	YES	7:00	YES	18:10	
			18NOV2009	YES	8:05	YES	18:45	
			19NOV2009	YES	7:30	YES	17:55	
			20NOV2009	YES	8:20	YES	18:00	
			21NOV2009	YES	8:25	YES	18:45	
			22NOV2009	YES	9:30	YES	18:00	
			23NOV2009	YES	7:25	YES	18:20	
			24NOV2009	YES	7:45	YES	18:10	
			25NOV2009	YES	7:45	YES	17:00	
			26NOV2009	YES	6:50	YES	17:10	
			27NOV2009	YES	8:00	YES	18:20	
			28NOV2009	YES	9:20	YES	17:40	
			29NOV2009	YES	9:25	YES	18:35	
			30NOV2009	YES	6:45	YES	18:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	01DEC2009	YES	7:10	YES	17:20	
			02DEC2009	YES	7:25	YES	17:50	
			03DEC2009	YES	7:40	YES	17:10	
			04DEC2009	YES	7:55	YES	19:10	
			05DEC2009	YES	9:10	YES	17:40	
			06DEC2009	YES	9:10	YES	17:30	
			07DEC2009	YES	7:05	YES	17:40	
			08DEC2009	YES	8:35	YES	17:10	
			09DEC2009	YES	8:15	YES	17:40	
			10DEC2009	YES	8:15	YES	16:35	
			11DEC2009	YES	7:50	YES	17:25	
			12DEC2009	YES	8:45	YES	18:35	
			13DEC2009	YES	9:20	YES	17:40	
			14DEC2009	YES	7:05	YES	17:35	
			15DEC2009	YES	7:15	YES	17:20	
			16DEC2009	YES	7:45	YES	17:40	
			17DEC2009	YES	8:00	YES	17:05	
			18DEC2009	YES	8:20	YES	16:45	
			19DEC2009	YES	8:45	YES	18:16	
			20DEC2009	YES	8:55	YES	18:00	
			21DEC2009	YES	7:15	YES	18:45	
			22DEC2009	YES	7:30	YES	18:20	
			23DEC2009	YES	9:00	YES	18:12	
			24DEC2009	YES	9:00	YES	19:00	
			25DEC2009	YES	9:25	YES	18:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	26DEC2009	YES	9:45	YES	18:00	
			27DEC2009	YES	9:55	YES	18:10	
			28DEC2009	YES	7:30	YES	18:20	
			29DEC2009	YES	7:55	YES	18:35	
			30DEC2009	YES	10:00	YES	18:55	
			31DEC2009	YES	10:30	YES	18:00	
			01JAN2010	YES	10:30	YES	19:20	
			02JAN2010	YES	8:30	YES	18:40	
			03JAN2010	YES	8:40	YES	18:15	
			04JAN2010	YES	7:15	YES	18:40	
			05JAN2010	YES	7:20			
			05JAN2010	YES	7:20	YES	18:25	
			06JAN2010	YES	9:25	YES	18:30	
			07JAN2010	YES	7:30	YES	18:35	
			08JAN2010	YES	9:00	YES	18:30	
			09JAN2010	YES	9:00	YES	18:55	
			10JAN2010	YES	9:30	YES	18:25	
			11JAN2010	YES	7:25	YES	18:20	
			12JAN2010	YES	7:35	YES	18:20	
			13JAN2010	YES	7:10	YES	18:50	
			13JAN2010	YES	9:55			abends vergessen
			14JAN2010	YES	8:20	YES	18:00	
			15JAN2010	YES	9:30	YES	18:15	
			16JAN2010	YES	9:10	YES	18:35	
			17JAN2010	YES	9:20		18:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	18JAN2010	YES	7:00	YES	18:00	
			19JAN2010	YES	7:35	YES	18:40	
			20JAN2010	YES	8:00	YES	18:30	
			21JAN2010	YES	8:00	YES	18:10	
			22JAN2010	YES	8:45	YES	18:15	
			23JAN2010	YES	8:30	YES	18:15	
			24JAN2010	YES	8:50	YES	18:10	
			25JAN2010	YES	7:20	YES	19:40	
			26JAN2010	YES	7:25	YES	18:20	
			27JAN2010	YES	8:25	YES	18:20	
			28JAN2010	YES	7:55	YES	18:40	
			29JAN2010	YES	7:45	YES	17:45	
			30JAN2010	YES	8:25	YES	17:10	
			31JAN2010	YES	8:35	YES	18:00	
			01FEB2010	YES	7:00	YES	18:00	
			02FEB2010	YES	7:20	YES	18:10	
			03FEB2010	YES	7:30	YES	18:00	
			04FEB2010	YES	8:35	YES	18:25	
			05FEB2010	YES	8:00	YES	18:25	
			06FEB2010	YES	8:30	YES	18:05	
			07FEB2010	YES	7:50	YES	17:45	
			08FEB2010	YES	6:50	YES	17:55	
			09FEB2010	YES	7:10	YES	19:00	
			10FEB2010	YES	7:30	YES	17:50	
			11FEB2010	YES	8:00	YES	17:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	12FEB2010	YES	7:45	YES	19:15	abends vergessen bzw. nach dem Essen eingenommen
			13FEB2010	YES	8:00	YES	19:00	
			14FEB2010	YES	8:20	YES	17:45	
			15FEB2010	YES	7:00	YES	18:40	
			16FEB2010	YES	8:00	YES	19:00	
			17FEB2010	YES	8:40	YES	18:00	
			18FEB2010	YES	6:35	YES	17:35	
			19FEB2010	YES	8:00	YES	18:00	
			20FEB2010	YES	7:45	YES	18:00	
			21FEB2010	YES	9:10	YES	17:00	
			22FEB2010	YES	7:00	YES	18:05	
			23FEB2010	YES	7:00	YES	19:00	
			24FEB2010	YES	7:30	YES	18:20	
			25FEB2010	YES	7:30	YES	20:00	
			26FEB2010	YES	7:30	YES	18:20	
			27FEB2010	YES	8:45	YES	19:00	
			28FEB2010	YES	9:00	YES	19:00	
			01MAR2010	YES	6:30	YES	18:40	
			02MAR2010	YES	7:20	YES	19:00	
			03MAR2010	YES	7:15	YES	17:40	
			04MAR2010	YES	8:45	YES	18:15	
			05MAR2010	YES	8:25	YES	17:00	
			06MAR2010	YES	8:45	YES	20:10	
			07MAR2010	YES	9:50	YES	18:35	
			08MAR2010	YES	8:50	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	09MAR2010	YES	8:25	YES	19:00	
			10MAR2010	YES	7:20	YES	18:25	
			11MAR2010	YES	8:00	YES	18:15	
			12MAR2010	YES	7:45	YES	18:35	
			14MAR2010	YES	7:35	YES	17:45	
			15MAR2010	YES	6:30	YES	18:30	
			16MAR2010	YES	7:30	YES	18:00	
			17MAR2010	YES	7:00	YES	18:45	
			18MAR2010	YES	7:15	YES	17:50	
			19MAR2010	YES	7:30	YES	18:45	
			20MAR2010	YES	8:35	YES	18:00	
			21MAR2010	YES	9:00	YES	17:45	
			22MAR2010	YES	7:00	YES	18:55	
			23MAR2010	YES	6:55	YES	17:49	
			24MAR2010	YES	7:40	YES	18:00	
			25MAR2010	YES	7:00	YES	19:00	
			26MAR2010	YES	7:30	YES	18:00	
			27MAR2010	YES	7:45	NO		abends vergessen
			28MAR2010	YES	9:10	YES	18:35	
			29MAR2010	YES	7:00	YES	19:00	
			30MAR2010	YES	7:25	YES	18:45	
			31MAR2010	YES	8:00	YES	19:00	
			01APR2010	YES	8:00	YES	19:00	
			02APR2010	YES	7:40	YES	18:15	
			03APR2010	YES	8:40	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	002	1	04APR2010	YES	6:30	YES	18:15	
			05APR2010	YES	8:15	YES	18:30	
			06APR2010	YES	7:10	YES	18:15	
			07APR2010	YES	8:35	YES	18:00	
			08APR2010	YES	7:30	YES	18:00	
			09APR2010	YES	8:00	YES	18:20	
			10APR2010	YES	7:30	YES	18:25	
			11APR2010	YES	8:00			abends vergessen
			12APR2010	YES	7:00	YES	7:45	
			13APR2010	YES	7:00	YES	18:20	
			14APR2010	YES	7:40	YES	18:00	
			15APR2010	YES	7:30	YES	17:35	
			16APR2010	YES	8:50	YES	18:55	
			17APR2010	YES	8:40	YES	17:25	
			18APR2010	YES	8:10	YES	18:35	
			19APR2010	YES	6:45	YES	17:55	
			20APR2010	YES	7:10	YES	17:30	
			21APR2010	YES	6:00	YES	17:35	
			22APR2010	YES	5:00			
	004	1	16JUL2009	YES	14:30	YES	18:00	
			17JUL2009	YES	8:00	YES	18:00	
			18JUL2009	YES	7:30	YES	18:00	
			19JUL2009	YES	7:45	YES	18:00	
			20JUL2009	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	004	1	21JUL2009	YES	7:30	YES	18:00	
			22JUL2009	YES	7:30	YES	18:30	
			23JUL2009	YES	7:30	YES	18:00	
			24JUL2009	YES	7:30	YES	18:00	Immer noch Schmerzen an den Hüften
			25JUL2009	YES	7:30	YES	18:00	
			26JUL2009	YES	8:00	YES	18:00	
			27JUL2009	YES	7:30	YES	18:00	
			28JUL2009	YES	7:30	YES	19:00	
			29JUL2009	YES	7:30	YES	18:00	
			30JUL2009	YES	7:00	YES	18:00	Immer noch Schmerzen im Rücken + Hüfte
			31JUL2009	YES	8:00	YES	18:00	Immer noch Schmerzen im Rücken + Hüfte
			01AUG2009	YES	8:00	YES	18:00	
			02AUG2009	YES	8:30	YES	18:30	
			03AUG2009	YES	7:30	YES	18:00	
			04AUG2009	YES	7:30		18:30	
			05AUG2009	YES	8:00	YES	20:00	
			06AUG2009	YES	7:45	YES	20:00	
			07AUG2009	YES	8:00	YES	20:00	
			08AUG2009	YES	8:00	YES	18:30	
			09AUG2009	YES	8:00	YES	20:00	
			10AUG2009	YES	8:30	YES	18:30	
			11AUG2009	YES	7:30	YES	7:15	
			12AUG2009	YES	6:30			
	006	2	27FEB2010	YES	7:45	YES	16:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	28FEB2010	YES	7:00	YES	17:00	
			01MAR2010	YES	7:10	YES	17:05	
			02MAR2010	YES	7:00	YES	17:00	
			03MAR2010	YES	7:06	YES	16:30	
			04MAR2010	YES	7:00	YES	16:45	
			05MAR2010	YES	7:00	YES	17:00	
			06MAR2010	YES	7:00	YES	17:30	
			07MAR2010	YES	7:10	YES	17:15	
			08MAR2010	YES	7:00	YES	16:45	
			09MAR2010	YES	7:00	YES	17:15	
			10MAR2010	YES	7:00	YES	17:05	
			11MAR2010	YES	7:00	YES	17:00	
			12MAR2010	YES	7:00	YES	16:45	
			13MAR2010	YES	7:00	YES	16:45	
			14MAR2010	YES	7:55	YES	16:45	
			15MAR2010	YES	7:00	YES	16:40	
			16MAR2010	YES	7:00	YES	16:50	
			17MAR2010	YES	6:50	YES	16:20	
			18MAR2010	YES	7:00	YES	16:40	
			19MAR2010	YES	7:00	YES	16:30	
			20MAR2010	YES	7:00	YES	16:30	
			21MAR2010	YES	7:00	YES	16:40	
			22MAR2010	YES	7:00	YES	16:45	
			23MAR2010	YES	7:00	YES	16:45	
			24MAR2010	YES	7:25	YES	17:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	25MAR2010	YES	7:00	YES	17:25	
			26MAR2010	YES	7:00			
			26MAR2010			YES	17:00	Frühpille im Heft 1 morgens genommen-eingenommen
			27MAR2010	YES	7:00	YES	17:20	
			28MAR2010	YES	8:05	YES	16:35	
			29MAR2010	YES	7:00	YES	18:35	
			30MAR2010	YES	7:10	YES	16:25	
			31MAR2010	YES	7:03	YES	16:25	
			01APR2010	YES	7:03	YES	16:30	
			02APR2010	YES	7:00	YES	16:30	
			03APR2010	YES	7:02	YES	16:45	
			04APR2010	YES	7:00	YES	16:45	
			05APR2010	YES	7:00	YES	17:40	
			06APR2010	YES	7:00	YES	16:45	
			07APR2010	YES	7:00	YES	16:30	
			08APR2010	YES	7:00	YES	16:45	
			09APR2010	YES	7:00	YES	16:30	
			10APR2010	YES	7:00	YES	17:10	
			11APR2010	YES	7:00	YES	16:30	
			12APR2010	YES	7:00	YES	16:45	
			13APR2010	YES	7:00	YES	16:30	
			14APR2010	YES	7:00	YES	16:30	
			15APR2010	YES	7:00	YES	16:30	
			16APR2010	YES	7:10	YES	17:35	
			17APR2010	YES	7:00	YES	16:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	18APR2010	YES	7:00	YES	17:15	
			19APR2010	YES	7:00	YES	17:50	
			20APR2010	YES	7:00	YES	16:30	
			21APR2010	YES	7:00	YES	16:45	
			22APR2010	YES	7:00	YES	17:25	
			23APR2010	YES	7:00			
			24APR2010	YES	7:00	YES	17:00	
			25APR2010	YES	7:00	YES	16:30	
			26APR2010	YES	7:07		16:30	
			27APR2010	YES	7:00	YES	17:05	
			28APR2010	YES	7:05	YES	16:45	
			29APR2010	YES	7:00	YES	16:50	
			30APR2010	YES	7:00	YES	16:30	
			01MAY2010	YES	7:00	YES	17:10	
			02MAY2010	YES	7:00	YES	17:00	
			03MAY2010	YES	7:00	YES	17:45	
			04MAY2010	YES	7:00	YES	17:00	
			05MAY2010	YES	7:13	YES	17:30	
			06MAY2010	YES	7:00	YES	17:10	
			07MAY2010	YES	7:00	YES	17:00	
			08MAY2010	YES	7:00	YES	17:00	
			09MAY2010	YES	7:00	YES	16:45	
			10MAY2010	YES	7:45	YES	16:45	
			11MAY2010	YES	7:00			
			12MAY2010	YES	7:00			

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	13MAY2010	YES	7:00	YES	17:00	
			14MAY2010	YES	7:00	YES	16:30	
			15MAY2010	YES	7:00	YES	17:10	
			16MAY2010	YES	7:00	YES	17:55	
			17MAY2010	YES	7:00	YES	17:55	
			18MAY2010	YES	7:06			
			19MAY2010	YES	7:02	YES	17:00	
			20MAY2010	YES	7:00	YES	17:15	
			21MAY2010	YES	7:00			
			21MAY2010	YES		YES	18:15	1. Pille im anderen Buch!
			22MAY2010	YES	6:30	YES	18:00	
			23MAY2010	YES	6:30	YES	17:10	
			24MAY2010	YES	7:00		7:30	
			25MAY2010	YES	6:30	YES	17:10	
			26MAY2010	YES	7:32	YES	17:35	
			27MAY2010	YES	7:00	YES	18:25	
			28MAY2010	YES	7:00		17:05	
			29MAY2010	YES	7:00	YES	17:30	
			30MAY2010	YES	7:00	YES	17:00	
			31MAY2010	YES	7:00	YES	17:00	
			01JUN2010	YES	7:40	YES	15:05	
			02JUN2010	YES	7:00	YES	13:05	
			03JUN2010	YES	7:15	YES	17:10	
			04JUN2010	YES	6:02	YES	17:40	Originaleintrag: 60:02
			05JUN2010	YES	7:00	YES	17:40	

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	06JUN2010	YES	7:00	YES	17:45	
			07JUN2010	YES	7:00	YES	17:25	
			08JUN2010	YES	7:00	YES	17:10	
			09JUN2010	YES	7:00	YES	17:35	
			10JUN2010	YES	7:00	YES	17:10	
			11JUN2010	YES	7:12	YES	17:45	
			12JUN2010	YES	7:26	YES	17:42	
			13JUN2010	YES	7:00	YES	17:30	
			14JUN2010	YES	7:00	YES	17:42	
			15JUN2010	YES	7:00	YES	16:20	
			16JUN2010	YES	7:00	YES	17:30	
			17JUN2010	YES	7:00	YES	17:15	
			18JUN2010	YES	7:00	YES	17:10	
			19JUN2010	YES	7:21	YES	17:30	
			20JUN2010	YES	7:00	YES	17:30	
			21JUN2010	YES	7:00	YES	18:00	
			22JUN2010	YES	7:29	YES	16:50	
			23JUN2010	YES	7:12	YES	17:20	
			24JUN2010	YES	7:02	YES	17:25	
			25JUN2010	YES	7:00	YES	17:10	
			26JUN2010	YES	7:00	YES	16:50	
			27JUN2010	YES	7:59	YES	17:20	
			28JUN2010	YES	7:20	YES	17:00	
			29JUN2010	YES	7:00	YES	17:10	
			30JUN2010	YES	7:00	YES	17:52	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	01JUL2010	YES	7:05	YES	17:30	
			02JUL2010	YES	7:00	YES	17:40	
			03JUL2010	YES	7:00	YES	17:20	
			04JUL2010	YES	7:00	YES	17:00	
			05JUL2010	YES	7:02	YES	17:25	
			06JUL2010	YES	7:16	YES	17:15	
			07JUL2010	YES	7:00	YES	17:50	
			08JUL2010	YES	7:00	YES	17:30	
			09JUL2010	YES	7:00	YES	17:30	
			10JUL2010	YES	7:00	YES	17:30	
			11JUL2010	YES	7:01	YES	17:45	
			12JUL2010	YES	7:00	YES	17:00	
			13JUL2010	YES	6:00	YES	17:50	
			14JUL2010	YES	7:00	YES	17:30	
			15JUL2010	YES	7:00	YES	17:30	
			16JUL2010	YES	6:35	YES	17:15	
			17JUL2010	YES	7:03	YES	17:00	
			18JUL2010	YES	8:05	YES	17:30	
			19JUL2010	YES	7:00	YES	17:30	
			20JUL2010	YES	7:00	YES	17:20	
			21JUL2010	YES	7:00	YES	17:40	
			22JUL2010	YES	7:00	YES	17:30	
			23JUL2010	YES	7:00	YES	17:30	
			24JUL2010	YES	7:00	YES	17:30	
			25JUL2010	YES	7:00	YES	17:25	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	26JUL2010	YES	7:15	YES	17:30	
			27JUL2010	YES	7:00	YES	17:30	
			28JUL2010	YES	7:00	YES	17:30	
			29JUL2010	YES	7:45	YES	17:30	
			30JUL2010	YES	7:03	YES	17:30	
			31JUL2010	YES	7:01	YES	17:30	
			01AUG2010	YES	7:01	YES	17:30	
			02AUG2010	YES	7:00	YES	17:30	
			03AUG2010	YES	7:01	YES	17:45	
			04AUG2010	YES	7:03	YES	17:30	
			05AUG2010	YES	7:00	YES	17:00	
			06AUG2010	YES	7:00	YES	17:32	
			07AUG2010	YES	7:00	YES	17:30	
			08AUG2010	YES	7:00	YES	17:45	
			09AUG2010	YES	7:37	YES	18:00	
			10AUG2010	YES	7:07	YES	17:30	
			11AUG2010	YES	7:00		17:30	
			12AUG2010	YES	7:00	YES	17:30	
			13AUG2010	YES	7:30			
			14AUG2010	YES	7:45	YES	17:40	
			15AUG2010	YES	7:21	YES	17:30	
			16AUG2010	YES	7:00	YES	17:15	
			17AUG2010	YES	7:00	YES	18:00	
			18AUG2010	YES	7:01	YES	17:50	
			19AUG2010	YES	7:02	YES	17:40	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	20AUG2010	YES	7:00	YES	17:30	
			21AUG2010	YES	7:17	YES	17:00	
			22AUG2010	YES	7:03	YES	17:30	
			23AUG2010	YES	7:32	YES	17:30	
			24AUG2010	YES	8:20	YES	18:30	
			25AUG2010	YES	7:00	YES	17:30	
			26AUG2010	YES	7:01	YES	18:15	
			27AUG2010	YES	7:22	YES	19:00	
			28AUG2010	YES	7:50	YES	17:36	
			29AUG2010	YES	7:57	YES	17:30	
			30AUG2010	YES	7:02	YES	17:30	
			31AUG2010	YES	7:07	YES	17:30	
			01SEP2010	YES	7:00	YES	17:30	
			02SEP2010	YES	7:30	YES	17:30	
			03SEP2010	YES	7:00	YES	17:30	
			04SEP2010	YES	7:08	YES	17:30	
			05SEP2010	YES	7:00	YES	17:45	
			06SEP2010	YES	7:00	YES	17:30	
			07SEP2010	YES	7:00	YES	17:30	
			08SEP2010	YES	7:00	YES	17:30	
			09SEP2010	YES	7:18	YES	18:00	
			10SEP2010	YES	7:00	YES	17:30	
			11SEP2010	YES	7:02	YES	17:30	
			12SEP2010	YES	7:00	YES	17:30	
			13SEP2010	YES	7:52	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	14SEP2010	YES	7:00	YES	18:00	
			15SEP2010	YES	6:58	YES	17:45	
			16SEP2010	YES	6:58	YES	17:30	
			17SEP2010	YES	7:50	YES	17:30	
			18SEP2010	YES	7:02	YES	17:30	
			19SEP2010	YES	7:00	YES	17:30	
			20SEP2010	YES	8:00	YES	20:09	um 17:31 Uhr eingenommen
			21SEP2010	YES	7:33	YES	17:30	
			22SEP2010	YES	6:59	YES	17:45	
			23SEP2010	YES	7:01	YES	17:30	
			24SEP2010	YES	7:55	YES	17:30	
			25SEP2010	YES	8:00	YES	17:30	
			26SEP2010	YES	7:30	YES	18:00	
			27SEP2010	YES	7:30	YES	17:15	
			28SEP2010	YES	7:00	YES	17:45	
			29SEP2010	YES	7:50	YES	17:30	
			30SEP2010	YES	7:30	YES	17:30	
			01OCT2010	YES	7:00	YES	17:30	
			02OCT2010	YES	7:50	YES	17:45	
			03OCT2010	YES	8:00	YES	17:00	
			04OCT2010	YES	7:35	YES	17:30	
			05OCT2010	YES	7:00	YES	17:30	
			06OCT2010	YES	7:00	YES	17:30	
			07OCT2010	YES	8:32	YES	17:30	
			08OCT2010	YES	7:15	YES	17:40	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	09OCT2010	YES	7:45	YES	17:45	
			10OCT2010	YES	7:15	YES	17:30	
			11OCT2010	YES	7:00	YES	17:45	
			12OCT2010	YES	7:15	YES	17:30	
			13OCT2010	YES	7:20	YES	17:30	
			14OCT2010	YES	7:01	YES	17:30	
			15OCT2010	YES	7:45	YES	17:45	
			16OCT2010	YES	7:01	YES	17:30	
			17OCT2010	YES	7:20	YES	17:30	
			18OCT2010	YES	7:22	YES	17:45	
			19OCT2010	YES	7:20	YES	17:45	
			20OCT2010	YES	8:00	YES	18:00	
			21OCT2010	YES	7:50	YES	18:15	
			22OCT2010	YES	8:02	YES	17:30	
			23OCT2010	YES	6:30	YES	17:15	
			24OCT2010	YES	8:30	YES	18:00	
			25OCT2010	YES	8:00	YES	17:30	
			26OCT2010	YES	7:02	YES	17:30	
			27OCT2010	YES	7:52	YES	17:30	
			28OCT2010	YES	7:00	YES	17:30	
			29OCT2010	YES	7:17	YES	17:30	
			30OCT2010	YES	7:51	YES	17:30	
			31OCT2010	YES	8:17	YES	17:30	
			01NOV2010	YES	7:17	YES	17:45	
			02NOV2010	YES	7:31	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	03NOV2010	YES	7:20	YES	17:45	
			04NOV2010	YES	6:12			
			05NOV2010	YES	7:15	YES	17:30	
			06NOV2010	YES	7:10	YES	17:30	
			07NOV2010	YES	7:35	YES	17:30	
			08NOV2010	YES	8:10	YES	18:00	
			09NOV2010	YES	7:20	YES	17:45	
			10NOV2010	YES	7:40	YES	17:30	10:10 eine Aspirin.
			11NOV2010	YES	7:56	YES	17:30	
			12NOV2010	YES	8:00	YES	17:30	
			13NOV2010	YES	7:33	YES	17:30	
			14NOV2010	YES	7:57	YES	17:30	
			15NOV2010	YES	8:15	YES	17:30	
			16NOV2010	YES	7:15	YES	17:30	
			17NOV2010	YES	7:30	YES	17:30	
			18NOV2010	YES	7:06	YES	17:30	
			19NOV2010	YES	8:15	YES	17:30	
			20NOV2010	YES	7:09	YES	17:30	
			21NOV2010	YES	8:30	YES	17:30	
			22NOV2010	YES	8:15	YES	17:30	
			23NOV2010	YES	7:55	YES	17:30	
			24NOV2010	YES	8:00	YES	17:30	
			25NOV2010	YES	7:32	YES	17:30	
			26NOV2010	YES	8:41	YES	17:45	
			27NOV2010	YES	7:21	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	28NOV2010	YES	8:00	YES	17:45	
			29NOV2010	YES	8:13	YES	18:00	
			30NOV2010	YES	8:25	YES	18:00	
			01DEC2010	YES	7:45	YES	17:30	
			03DEC2010	YES	8:05	YES	17:30	
			04DEC2010	YES	8:09	YES	17:30	
			05DEC2010	YES	7:46	YES	17:30	
			07DEC2010	YES	8:17	YES	17:30	
			08DEC2010	YES	8:30	YES	17:30	
			09DEC2010	YES	8:45	YES	17:30	
			10DEC2010	YES	8:27	YES	17:30	
			11DEC2010	YES	8:05	YES	17:30	
			12DEC2010	YES	9:25	YES	17:30	
			13DEC2010	YES	8:37	YES	17:30	
			14DEC2010	YES	8:25	YES	17:30	
			14DEC2010	YES	8:43	YES	17:45	
			15DEC2010	YES	8:51	YES	17:30	
			15DEC2010	YES	8:00	YES	17:45	
			16DEC2010	YES	8:30	YES	17:30	
			17DEC2010	YES	8:30	YES	17:30	
			18DEC2010		8:32	YES	18:00	
			19DEC2010	YES	8:35	YES	17:30	
			20DEC2010	YES	7:30	YES	17:30	
			21DEC2010	YES	7:13	YES	17:30	
			22DEC2010	YES	8:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	23DEC2010	YES	8:24	YES	18:00	
			26DEC2010	YES	8:29	YES	17:30	
			27DEC2010	YES	9:39	YES	17:30	
			28DEC2010	YES	8:30	YES	17:30	
			29DEC2010	YES	8:30	YES	17:30	
			30DEC2010	YES	8:30	YES	17:30	
			31DEC2010	YES	7:40	YES	17:30	
			01JAN2011	YES	9:22	YES	17:30	
			02JAN2011	YES	8:41	YES	17:30	
			03JAN2011	YES	8:30	YES	18:00	
			04JAN2011	YES	7:45	YES	17:30	
			05JAN2011	YES	7:45	YES	17:30	
			06JAN2011	YES	7:30	YES	17:30	
			07JAN2011	YES	9:05	YES	17:30	
			08JAN2011	YES	8:33	YES	17:30	
			09JAN2011	YES	8:38	YES	17:30	
			10JAN2011	YES	8:38	YES	17:30	
			11JAN2011	YES	8:35	YES	17:30	
			12JAN2011	YES	7:42	YES	17:30	
			13JAN2011	YES	7:48	YES	17:30	
			14JAN2011	YES	6:54	YES	17:30	
			15JAN2011	YES	8:34	YES	17:30	
			16JAN2011	YES	7:45	YES	17:30	
			17JAN2011	YES	7:57	YES	17:30	
			18JAN2011	YES	8:08	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	19JAN2011	YES	8:29	YES	17:30	
			20JAN2011	YES	9:04	YES	17:30	
			21JAN2011	YES	8:06	YES	17:30	
			22JAN2011	YES	8:12	YES	18:00	
			23JAN2011	YES	7:30	YES	17:30	
			24JAN2011	YES	8:57	YES	17:30	
			25JAN2011	YES	8:16	YES	17:30	
			26JAN2011	YES	8:00	YES	18:00	
			27JAN2011	YES	8:23	YES	17:30	
			28JAN2011	YES	8:21	YES	17:30	
			29JAN2011	YES	8:52	YES	17:30	
			30JAN2011	YES	9:00	YES	18:00	
			31JAN2011		8:30	YES	18:00	
			01FEB2011	YES	8:29	YES	17:30	
			02FEB2011	YES	8:30	YES	17:30	
			03FEB2011	YES	8:00	YES	17:30	
			04FEB2011	YES	8:15	YES	17:30	
			05FEB2011	YES	7:30	YES	17:30	
			06FEB2011	YES	7:30	YES	17:30	
			07FEB2011	YES	8:00	YES	17:45	
			08FEB2011	YES	8:00	YES	17:45	
			09FEB2011	YES	8:00	YES	18:00	
			10FEB2011	YES	7:30	YES	18:00	
			11FEB2011	YES	7:30	YES	17:30	
			12FEB2011	YES	8:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	006	2	13FEB2011	YES	8:00	YES	17:30	
			14FEB2011	YES	7:30	YES	17:30	
			15FEB2011	YES	7:30	YES	17:30	
			16FEB2011	YES	8:00	YES	17:30	
			17FEB2011	YES	8:00	YES	17:30	
			18FEB2011	YES	8:00	YES	18:00	
			19FEB2011	YES	8:00	YES	18:00	
			20FEB2011	YES	7:30	YES	18:00	
			21FEB2011	YES	8:30	YES	17:45	
			22FEB2011	YES	8:00	YES	17:45	
			23FEB2011	YES	7:30	YES	17:30	
	010	1	23OCT1998	YES	8:30	YES	18:00	
			21JUL2009	YES	11:30	YES	18:45	
			22JUL2009	YES	7:50	YES	19:40	
			23JUL2009	YES	9:00	YES	19:00	
			24JUL2009	YES	9:40	YES	20:00	
			25JUL2009	YES	8:50	YES	21:30	
			26JUL2009	YES	7:50	NO		blood clot in eye in the Ann, leichte Rötung des Auges ØAE. Came home after midnight from family medical emergency in Nürnberg (Bruder betreffend)
			27JUL2009	YES	11:10	YES	20:30	
			28JUL2009	YES	11:15	YES	21:05	
			29JUL2009	YES	8:40	YES	21:20	
			30JUL2009	YES	8:05	YES	21:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	010	1	31JUL2009	YES	8:15	YES	20:50	
			01AUG2009	YES	9:50	YES	23:15	
			02AUG2009	YES	8:45	YES	21:45	
			03AUG2009	YES	8:50	YES	21:35	
			04AUG2009	YES	9:45	YES	20:20	
			05AUG2009	YES	8:30	YES	20:55	
			06AUG2009	YES	10:35	YES	20:30	
			07AUG2009	YES	7:50	YES	21:00	
			08AUG2009	YES	9:00	YES	20:55	
			09AUG2009	YES	9:40	YES	20:40	
			10AUG2009	YES	9:55	YES	20:45	
			11AUG2009	YES	9:35	YES	22:30	
			12AUG2009	YES	9:35	YES	19:55	
			13AUG2009	YES	10:00	YES	21:00	
			14AUG2009	YES	9:50	YES	22:00	
			15AUG2009	YES	10:00	YES	22:00	
			16AUG2009	YES	10:30	YES	22:35	
			17AUG2009	YES	10:20	YES	22:50	
			18AUG2009	YES	11:00	YES	22:00	
			19AUG2009	YES	10:30	YES	21:55	
			20AUG2009			YES	9:30	
			20AUG2009	YES	7:00			
			21AUG2009	YES	7:10	YES	20:45	
			22AUG2009	YES	7:55	YES	20:30	
			23AUG2009	YES	8:10	YES	20:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	010	1	24AUG2009	YES	8:55	YES	20:00	
			25AUG2009	YES	13:00	YES	20:55	
			26AUG2009	YES	8:15	YES	20:10	
			27AUG2009	YES	7:45	YES	20:00	τ08:00 h Disoriented about affrat work in A.M. τ1 h. ØAE sax krankheitsbedingt
			28AUG2009	YES	9:35	YES	22:00	
			29AUG2009	YES	10:55	YES	20:30	
			30AUG2009	YES	9:55	YES	19:15	
			31AUG2009	YES	8:35	YES	19:15	
			01SEP2009	YES	10:50	NO		Notifation of brothers death, Anruf über Tod des Bruders
			02SEP2009	YES	10:00	YES	21:15	
			03SEP2009	YES	8:00	NO		Juneval in Nürnberg of brother, Beerdigung des Bruders
			04SEP2009	YES	11:15	YES	19:50	
			05SEP2009	YES	10:30	YES	19:55	
			06SEP2009	YES	10:00	NO		
			07SEP2009	YES	8:00	YES	20:00	
			08SEP2009	YES	9:00	YES	20:55	
			09SEP2009	YES	8:30	YES	20:15	
			10SEP2009	YES	11:00	YES	20:00	
			11SEP2009	YES	10:00	YES	20:50	
			12SEP2009	YES	9:30			I slept through sick! Ehefrau war krank, hatte durchgeschlafen u. damit Einnahme des Med. nicht erfolgt.

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	010	1	13SEP2009	YES	11:00	YES	10:30	
			14SEP2009	YES	10:45	YES	21:10	
			15SEP2009	YES	9:45	YES	19:35	
			16SEP2009	NO		YES	20:10	
			17SEP2009	YES	9:30	YES	21:00	
			18SEP2009	YES	11:10	YES	19:50	
			19SEP2009	YES	9:30	YES	19:15	
			20SEP2009	YES	8:30	YES	19:45	
			21SEP2009	YES	10:20	YES	18:50	
			22SEP2009	YES	8:30	YES	20:35	
			23SEP2009	YES	10:25	YES	21:30	
			24SEP2009	YES	9:30	YES	20:40	
			25SEP2009	YES	10:00	YES	19:15	
			26SEP2009	YES	9:50	YES	19:10	
			27SEP2009	YES	10:40	YES	19:20	
			28SEP2009	YES	9:50	YES	19:55	
			29SEP2009	YES	8:20	YES	19:55	
			30SEP2009	YES	8:20	YES	19:45	
			01OCT2009	YES	9:00	YES	19:00	
			02OCT2009	YES	9:55	YES	20:50	
			03OCT2009	YES	12:00	YES	21:15	Rash - came + went in morning 07:00 mit d Erwachen, Exanthem am Hals + Dekoltee, nach Rasur øAE
			04OCT2009	YES	11:00	YES	10:00	Pain in knee - for days "concern about research" pills

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	010	1	05OCT2009	YES	11:00	YES	20:10	Contact with Möhlstr. re the pain - Dr. Natale
			06OCT2009	NO		YES	19:40	Nüchtern in A.M. für Blutabnahme
			07OCT2009	YES	9:40	YES	20:20	
			08OCT2009	YES	10:10	YES	19:30	
			09OCT2009	YES	10:10	YES	20:00	
			10OCT2009	YES	10:30	YES	19:40	
			11OCT2009	YES	9:40	YES	20:50	
			12OCT2009	YES	6:15	YES		Uhrzeit: nicht bekannt
			13OCT2009	YES	6:10			
			13OCT2009			YES	18:45	
			14OCT2009	YES	7:40	YES	19:30	
			15OCT2009	YES	6:10	YES	19:25	
			16OCT2009	YES	6:00	YES	18:45	Sieht Gäste
			17OCT2009	YES	9:30	YES	18:40	Sieht "Gäste" bei uns - niemand ist da
			18OCT2009	YES	8:15		19:25	Painful knee barely able to walk
			19OCT2009	YES	8:30	YES	18:00	
			20OCT2009	YES	8:30	YES	18:00	
			21OCT2009	YES	8:30	YES	18:00	
			22OCT2009	YES	8:30	YES	18:00	
			24OCT2009	YES	8:30	YES	18:00	
			25OCT2009	YES	8:30	YES	18:00	
			26OCT2009	YES	8:30	YES	18:00	
			27OCT2009	YES	8:30	YES	18:00	
			28OCT2009	YES	8:30	YES	18:00	
			29OCT2009	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	010	1	30OCT2009	YES	8:30	YES	18:00	
			31OCT2009	YES	8:30	YES	18:00	
			01NOV2009	YES	8:30	YES	18:00	
			02NOV2009	YES	8:30	YES	18:00	
			03NOV2009	YES	8:30	YES	18:00	
			04NOV2009	YES	8:30	YES	18:00	
			05NOV2009	YES	8:30	YES	18:00	
			06NOV2009	YES	8:30	YES	18:00	
	012	1	19JUL2010	YES	13:00	YES	19:10	
			20JUL2010	YES	11:20	YES	19:00	
			21JUL2010	YES	8:30	YES	19:30	
			22JUL2010	YES	8:40	YES	18:50	
			23JUL2010	YES	8:30	YES	19:00	
			24JUL2010	YES	8:50	YES	19:10	
			25JUL2010	YES	8:45	YES	18:45	
			26JUL2010	YES	8:20	YES	19:20	
			27JUL2010	YES	8:25	YES	19:30	
			28JUL2010	YES	9:10	YES	18:40	
			29JUL2010	YES	8:30	NO	22:10	
			30JUL2010	YES	9:40	YES	19:10	
			31JUL2010	YES	8:55	YES	18:30	
			01AUG2010	YES	8:30	YES	18:30	
			02AUG2010	YES	9:10	YES	18:30	
			03AUG2010	YES	8:50	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	04AUG2010	YES	8:30	YES	18:30	
			05AUG2010	YES	8:55	YES	18:30	
			06AUG2010	YES	9:10	YES	18:30	
			07AUG2010	YES	8:50	YES	19:45	
			08AUG2010	YES	8:45	YES	18:40	
			09AUG2010	YES	8:30	YES	18:35	
			10AUG2010	YES	8:25	YES	18:30	
			11AUG2010	YES	9:05	YES	18:40	
			12AUG2010	YES	8:30	YES		
			12AUG2010			YES	18:30	09:00 h bei Frau Doktor Sax, Übernahme Visit Nr. 2
			13AUG2010	YES	8:50	YES	18:30	
			14AUG2010	YES	8:50	YES	18:40	
			15AUG2010	YES	8:50	YES	18:35	
			16AUG2010	YES	8:40	YES	18:40	
			17AUG2010	YES	8:30	YES	18:30	
			18AUG2010	YES	8:30	YES	18:35	
			19AUG2010	YES	9:10	YES	18:40	
			20AUG2010	YES	8:40	YES	18:30	
			21AUG2010	YES	8:35	YES	18:30	
			22AUG2010	YES	8:30	YES	18:30	
			23AUG2010	YES	8:40	YES	18:40	
			24AUG2010	YES	8:35	YES	18:30	
			25AUG2010	YES	8:40	YES	18:30	
			26AUG2010	YES	8:35	YES	18:35	
			27AUG2010	YES	8:35	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	28AUG2010	YES	8:30	YES	18:40	
			29AUG2010	YES	8:30	YES	18:30	
			30AUG2010	YES	8:40	YES	18:30	
			31AUG2010	YES	8:30	YES	18:50	
			01SEP2010	YES	8:30	YES	18:30	
			02SEP2010	YES	8:30	YES	18:50	
			03SEP2010	YES	8:35	YES	18:40	
			04SEP2010	YES	8:30	YES	18:30	
			05SEP2010	YES	8:45	YES	18:30	
			06SEP2010	YES	8:35	YES	18:30	
			07SEP2010	YES	8:30	YES	18:45	
			08SEP2010	YES	8:35	YES	20:15	
			09SEP2010	YES	8:40	YES	19:55	
			10SEP2010	YES	8:30	YES	18:40	
			11SEP2010	YES	8:35	YES	18:30	
			12SEP2010	YES	8:40	YES	18:30	
			13SEP2010	YES	8:35	YES	18:40	
			14SEP2010	YES	8:30	YES	18:30	
			15SEP2010	YES	8:30	YES	19:05	
			16SEP2010	YES	8:30	YES	18:10	
			17SEP2010	YES	8:35	YES	18:40	
			18SEP2010	YES	8:40	YES	21:10	
			19SEP2010	YES	8:30	YES	20:20	
			20SEP2010	YES	8:35	YES	18:30	
			21SEP2010	YES	8:30	YES	18:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	21SEP2010	YES	8:30	YES	18:40	
			22SEP2010	YES	8:30	YES	18:30	
			23SEP2010	YES	8:40	YES	18:30	
			24SEP2010	YES	8:20	YES	18:30	
			25SEP2010	YES	8:30	YES	18:30	
			26SEP2010	YES	8:35	YES	18:40	
			27SEP2010	YES	8:30	YES	18:30	
			28SEP2010	YES	8:35	YES	18:25	
			29SEP2010	YES	8:30	YES	18:30	
			30SEP2010	YES	8:40	YES	18:30	
			01OCT2010	YES	8:30	YES	18:50	
			02OCT2010	YES	8:30	YES	18:30	
			03OCT2010		8:30	YES	18:30	
			04OCT2010	YES	8:30	YES	18:30	
			05OCT2010	YES	8:34	YES	18:30	
			06OCT2010	YES	8:50	YES	18:50	
			07OCT2010	YES	8:50	YES	18:30	
			08OCT2010	YES	8:45	YES	18:40	
			09OCT2010	YES	8:30	YES	18:30	
			10OCT2010	YES	8:30	YES	18:30	
			11OCT2010	YES	8:30	YES	18:45	
			12OCT2010	YES	8:30	YES	18:30	
			13OCT2010	YES	8:30	YES		
			14OCT2010	YES	7:00			
			15OCT2010	YES	8:20	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	16OCT2010	YES	8:30	YES	18:00	
			17OCT2010	YES	8:30	YES	18:00	
			18OCT2010	YES	8:40	YES	18:00	
			19OCT2010	YES	8:30	YES	18:00	
			20OCT2010	YES	8:30	YES	18:00	
			21OCT2010	YES	8:35	YES	18:00	
			22OCT2010	YES	8:30	YES	18:00	
			23OCT2010	YES	8:45	YES	18:00	
			24OCT2010	YES	8:30	YES	18:00	
			25OCT2010	YES	8:45	YES	18:00	
			25OCT2010	YES	8:40	YES	18:00	
			25OCT2010	YES	8:30	YES	18:00	
			26OCT2010	YES	8:50	YES	18:00	
			27OCT2010	YES	8:55	YES	18:00	
			28OCT2010	YES	8:30	YES	18:00	
			29OCT2010	YES	8:40	YES	18:00	
			30OCT2010	YES	8:30	YES	18:00	
			01NOV2010	YES	8:40	YES	18:00	
			02NOV2010	YES	8:30	YES	18:00	
			03NOV2010	YES	8:35	YES	18:00	
			04NOV2010	YES	8:30	YES	18:00	
			05NOV2010	YES	8:10	YES	18:00	
			06NOV2010	YES	8:35	YES	18:00	
			07NOV2010	YES	8:30	YES	18:00	
			08NOV2010	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	09NOV2010	YES	8:30	YES	18:00	
			10NOV2010	YES	8:35	YES	18:00	
			11NOV2010	YES	8:30	YES	18:00	
			12NOV2010	YES	8:40	YES	18:00	
			13NOV2010	YES	8:50	YES	18:00	
			14NOV2010	YES	8:45	YES	18:00	
			15NOV2010	YES	8:30	YES	18:00	
			16NOV2010	YES	8:35	YES	18:00	
			17NOV2010	YES	8:40	YES	18:00	
			18NOV2010	YES	8:30	YES	18:00	
			19NOV2010	YES	8:30	YES	18:00	
			20NOV2010	YES	8:40	YES	18:00	
			21NOV2010	YES	8:30	YES	18:00	
			22NOV2010	YES	8:30	YES	18:00	
			23NOV2010	YES	8:40	YES	18:00	
			24NOV2010	YES	8:45	YES	18:00	
			25NOV2010	YES	8:35	YES	18:00	
			26NOV2010	YES	8:30	YES	18:00	
			27NOV2010	YES	8:30	YES	18:00	
			28NOV2010	YES	8:30	YES	18:00	
			29NOV2010	YES	8:35	YES	18:00	
			30NOV2010	YES	8:30	YES	18:00	
			01DEC2010	YES	9:10	YES	18:00	
			02DEC2010	YES	9:05	YES	18:00	
			03DEC2010	YES	9:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

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ACI-91	012	1	04DEC2010	YES	8:30	YES	18:00	
			05DEC2010	YES	8:40	YES	18:00	
			06DEC2010	YES	8:30	YES	18:00	
			07DEC2010	YES	8:30	YES	18:00	
			08DEC2010	YES	8:40	YES	18:00	
			09DEC2010	YES	8:30	YES	18:00	
			10DEC2010	YES	8:35	YES	18:00	
			11DEC2010	YES	8:40	YES	18:00	
			12DEC2010	YES	8:50	YES	18:00	
			13DEC2010	YES	8:30	YES	18:00	
			14DEC2010	YES	8:50	YES	18:00	
			15DEC2010	YES	8:40	YES	18:00	
			16DEC2010	YES	7:50	YES	18:00	
			17DEC2010	YES	8:40	YES	18:00	
			18DEC2010	YES	8:30	YES	18:00	
			19DEC2010	YES	8:30	YES	18:00	
			20DEC2010	YES	8:30	YES	18:00	
			21DEC2010	YES	8:35	YES	18:00	
			22DEC2010	YES	8:30	YES	18:00	
			23DEC2010	YES	8:35	YES	18:00	
			24DEC2010	YES	8:40	YES	18:00	
			25DEC2010	YES	9:00	YES	18:00	
			26DEC2010	YES	8:30	YES	18:00	
			27DEC2010	YES	8:40	YES	18:00	
			28DEC2010	YES	8:30	YES	18:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	29DEC2010	YES	8:35	YES	18:00	
			30DEC2010	YES	8:30	YES	18:00	
			31DEC2010	YES	8:30	YES	18:00	
			02JAN2011	YES	8:30	YES	18:00	
			03JAN2011	YES	8:40	YES	18:00	
			04JAN2011	YES	8:30	YES	18:00	
			05JAN2011	YES	8:50	YES	18:00	
			06JAN2011	YES	8:40	YES	18:00	
			07JAN2011	YES	8:30	YES	18:00	
			08JAN2011	YES	8:45	YES	18:00	
			09JAN2011	YES	8:40	YES	18:00	
			10JAN2011	YES	8:30			
			11JAN2011	YES	8:30	YES	18:30	
			12JAN2011	YES	8:30	YES	18:40	
			13JAN2011	YES	8:30	YES	18:30	
			14JAN2011	YES	8:30	YES	18:30	
			15JAN2011	YES	8:30	YES	18:30	
			16JAN2011	YES	8:30	YES	18:50	
			17JAN2011	YES	8:30	YES	18:50	
			18JAN2011	YES	8:30	YES	18:30	
			19JAN2011	YES	8:30	YES	19:10	
			20JAN2011	YES	8:40	YES	18:30	
			21JAN2011	YES	8:30	YES	18:40	
			22JAN2011	YES	8:30	YES	18:30	
			23JAN2011	YES	8:30	YES	18:30	

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	24JAN2011	YES	8:30	YES	21:30	
			25JAN2011	YES	8:50	YES	8:30	
			26JAN2011	YES	8:30	YES	18:30	
			27JAN2011	YES	8:35	YES	18:30	
			28JAN2011	YES	8:30	YES	18:40	
			29JAN2011	YES	8:30	YES	18:30	
			30JAN2011	YES	8:30	YES	18:30	
			31JAN2011	YES	8:30	YES	18:30	
			01FEB2011	YES	8:30	YES	18:30	
			02FEB2011	YES	8:30	YES	18:30	
			03FEB2011	YES	8:30	YES	18:30	
			04FEB2011	YES	8:30	YES	18:30	
			05FEB2011	YES	8:30	YES	18:30	
			06FEB2011	YES	8:30	YES	18:30	
			07FEB2011	YES	8:30	YES	18:30	
			08FEB2011	YES	8:30	YES	18:30	
			09FEB2011	YES	8:30	YES	18:30	
			10FEB2011	YES	8:30	YES	18:30	
			11FEB2011	YES	8:30	YES	18:30	
			12FEB2011	YES	8:30	YES	18:30	
			13FEB2011	YES	8:30	YES	18:30	
			14FEB2011	YES	8:30	YES	18:30	
			15FEB2011	YES	8:30	YES	18:30	
			16FEB2011	YES	8:30	YES	20:10	
			17FEB2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	18FEB2011	YES	8:30	YES	18:30	
			19FEB2011	YES	8:30	YES	18:30	
			20FEB2011	YES	8:30	YES	20:10	
			21FEB2011	YES	8:50	YES	18:30	
			22FEB2011	YES	8:30	YES	18:30	
			23FEB2011	YES	8:30	YES	18:30	
			24FEB2011	YES	8:40	YES	18:30	
			25FEB2011	YES	8:30	YES	19:40	
			26FEB2011	YES	8:30	YES	18:30	
			27FEB2011	YES	8:50	YES	18:30	
			28FEB2011	YES	8:30	YES	18:30	
			01MAR2011	YES	8:30	YES	18:30	
			02MAR2011	YES	8:10	YES	18:30	
			03MAR2011	YES	8:30	YES	18:30	
			04MAR2011	YES	8:30	YES	18:30	
			05MAR2011	YES	8:30	YES	18:30	
			06MAR2011	YES	8:30	YES	18:30	
			07MAR2011	YES	8:30	YES	19:00	
			08MAR2011	YES	8:30	YES	18:30	
			09MAR2011	YES	8:30	YES	18:30	
			10MAR2011	YES	8:30	YES	18:30	
			11MAR2011	YES	8:30	YES	19:00	
			12MAR2011	YES	8:30	YES	18:30	
			13MAR2011	YES	8:30	YES	18:30	
			14MAR2011	YES	8:30	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	15MAR2011	YES	8:30	YES	18:30	
			16MAR2011	YES	8:30	YES	18:30	
			17MAR2011	YES	8:30	YES	18:30	
			18MAR2011	YES	8:30	YES	18:30	
			19MAR2011	YES	7:00	YES	18:30	
			20MAR2011	YES	8:30	YES	18:30	
			21MAR2011	YES	8:30	YES	18:30	
			22MAR2011	YES	8:30	YES	18:30	
			23MAR2011	YES	8:30	YES	18:30	
			24MAR2011	YES	8:30	YES	18:30	
			25MAR2011	YES	8:30	YES	18:30	
			26MAR2011	YES	8:30	YES	18:30	
			27MAR2011	YES	8:30	YES	18:30	
			28MAR2011	YES	8:30	YES	18:30	
			29MAR2011	YES	8:30	YES	18:30	
			30MAR2011	YES	8:30	YES	18:30	
			31MAR2011	YES	8:30	YES	18:30	
			01APR2011	YES	8:10			Termin zur V5 Visite, neues Med. + Tagebuch
			01APR2011	YES	8:30	YES	18:30	
			02APR2011	YES	8:40	YES	18:35	
			03APR2011	YES	8:40	YES	18:00	
			04APR2011	YES	8:30	YES	18:30	
			05APR2011	YES	8:35	YES	18:30	
			06APR2011	YES	8:30	YES	18:25	
			07APR2011	YES	8:35	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	08APR2011	YES	8:30	YES	19:30	
			09APR2011	YES	8:30	YES	18:30	
			10APR2011	YES	9:05	YES	18:30	
			11APR2011	YES	8:30	YES	18:30	
			12APR2011	YES	8:30	YES	18:30	
			13APR2011	YES	8:20	YES	18:00	
			14APR2011	YES	8:30	YES	18:30	
			15APR2011	YES	8:30	YES	18:25	
			16APR2011	YES	8:40	YES	19:30	
			17APR2011	YES	8:35	YES	18:30	
			18APR2011	YES	8:30	YES	18:30	
			19APR2011	YES	8:40	YES	18:30	
			20APR2011	YES	8:30	YES	18:30	
			21APR2011	YES	8:30	YES	18:30	
			22APR2011	YES	8:35	YES	18:35	
			23APR2011	YES	8:30	YES	18:30	
			24APR2011	YES	8:30	YES	18:30	
			25APR2011	YES	8:30	YES	18:50	
			26APR2011	YES	8:30	YES	18:30	
			27APR2011	YES	8:30	YES	18:30	
			28APR2011	YES	8:40	YES	18:30	
			29APR2011	YES	8:40	YES	18:30	
			30APR2011	YES	8:30	YES	18:30	
			01MAY2011	YES	8:40	YES	18:30	
			02MAY2011	YES	8:30	YES	18:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	03MAY2011	YES	8:30	YES	18:30	
			04MAY2011	YES	8:35	YES	18:30	
			05MAY2011	YES	8:30	YES	18:30	
			06MAY2011	YES	8:30	YES	18:40	
			07MAY2011	YES	8:00	YES	18:00	
			08MAY2011	YES	8:30	YES	18:30	
			09MAY2011	YES	8:30	YES	18:30	
			10MAY2011	YES	8:30	YES	18:20	
			11MAY2011	YES	8:30	YES	18:30	
			12MAY2011	YES	8:30	YES	18:30	
			13MAY2011	YES	8:40	YES	18:30	
			14MAY2011	YES	8:40	YES	18:40	
			15MAY2011	YES	8:30	YES	18:30	
			16MAY2011	YES	8:30	YES	18:30	
			17MAY2011	YES	8:10	YES	18:30	
			18MAY2011	YES	8:30	YES	18:30	
			19MAY2011	YES	8:30	YES	18:30	
			20MAY2011	YES	8:30	YES	18:30	
			21MAY2011	YES	8:30	YES	19:10	
			22MAY2011	YES	8:30	YES	18:30	
			23MAY2011	YES	8:30	YES	18:30	
			24MAY2011	YES	8:30	YES	18:30	
			25MAY2011	YES	8:30	YES	18:30	
			26MAY2011	YES	8:30	YES	18:30	
			27MAY2011	YES	8:50	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	28MAY2011	YES	8:30	YES	18:30	
			29MAY2011	YES	8:35	YES	18:30	
			30MAY2011	YES	8:30	YES	18:40	
			01JUN2011	YES	8:40	YES	18:50	
			02JUN2011	YES	8:45	YES	18:30	
			03JUN2011	YES	8:30	YES	18:30	
			04JUN2011	YES	8:30	YES	18:20	
			05JUN2011	YES	8:30	YES	18:30	
			06JUN2011	YES	8:40	YES	18:30	
			07JUN2011	YES	8:30	YES	18:30	
			08JUN2011	YES	8:30	YES	18:30	
			09JUN2011	YES	8:40	YES	18:30	
			10JUN2011	YES	8:30	YES	18:30	
			11JUN2011	YES	8:30	YES	18:40	
			12JUN2011	YES	8:50	YES	18:30	
			13JUN2011	YES	8:30	YES	18:20	
			14JUN2011	YES	8:30	YES	18:30	
			15JUN2011	YES	8:30	YES	18:30	
			16JUN2011	YES	8:30	YES	18:30	
			17JUN2011	YES	8:50	YES	18:30	
			18JUN2011	YES	8:35	YES	18:30	
			19JUN2011	YES	8:30	YES	18:30	
			20JUN2011	YES	8:35	YES	19:30	
			21JUN2011	YES	8:40	YES	18:30	
			22JUN2011	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	012	1	23JUN2011	YES	8:30	YES	18:20	
			24JUN2011	YES	8:30	YES	18:30	
			25JUN2011	YES	8:10	YES	18:30	
			26JUN2011	YES	8:30	YES	18:20	
			27JUN2011	YES	8:30	YES	18:20	
			28JUN2011	YES	8:30	YES	18:30	
			29JUN2011	YES	8:30	YES	18:30	
			30JUN2011	YES	8:40	YES	18:30	
			01JUL2011	YES	8:30	YES	18:30	
			02JUL2011	YES	8:30	YES	18:30	
			03JUL2011	YES	8:40	YES	18:50	
			04JUL2011	YES	8:30	YES	18:30	
			05JUL2011	YES	8:40	YES	18:30	
			06JUL2011	YES	8:30	YES	18:30	
			07JUL2011	YES	8:50	YES	18:20	
			08JUL2011	YES	8:30	YES	18:30	
			09JUL2011	YES	8:30	YES	18:30	
			10JUL2011	YES	8:30	YES	18:30	
			11JUL2011	YES	8:30	YES	18:30	
			12JUL2011	YES	8:30			
			01DEC2011	YES	9:20	YES	18:00	
	014	4	02NOV2009	YES	10:00	YES	21:00	1. Tabl. noch bei Fr. Dr. Ackl - Großhadern eingenommen.
			03NOV2009	YES	10:00	YES	22:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	04NOV2009	YES	10:00	YES	22:00	
			05NOV2009	YES	10:00	YES	22:15	
			06NOV2009	YES	9:30	YES	22:00	
			07NOV2009	YES	9:45	YES	22:10	
			08NOV2009	YES	10:15	YES	22:15	
			09NOV2009	YES	8:00	YES	21:00	
			10NOV2009	YES	10:00	YES	21:30	
			11NOV2009	YES	9:15	YES	10:00	
			12NOV2009	YES	9:30	YES	10:30	
			13NOV2009	YES	8:30	YES	10:00	
			14NOV2009	YES	10:00	YES	9:45	
			15NOV2009	YES	10:05	YES	9:45	
			16NOV2009	YES	10:15	YES	10:30	
			17NOV2009	YES	9:30	YES	9:15	
			18NOV2009	YES	9:45	YES	10:00	
			19NOV2009	YES	9:30	YES	11:00	
			20NOV2009	YES	9:30	YES	23:00	
			21NOV2009	YES	10:00	YES	23:10	
			22NOV2009	YES	10:30	YES	23:15	
			23NOV2009	YES	10:00	YES	23:00	
			24NOV2009	YES	10:10	YES	22:45	
			25NOV2009	YES	10:15	YES	22:15	
			26NOV2009	YES	10:00	YES	22:00	
			27NOV2009	YES	9:30	YES	21:45	
			28NOV2009	YES	9:30	YES	21:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	29NOV2009	YES	10:10	YES	22:00	
			30NOV2009	YES	9:45	YES	21:45	
			01DEC2009	YES	9:30	YES	22:30	
			02DEC2009	YES	10:00	YES	22:00	
			03DEC2009	NO		YES		Restpackung mit 8 Tabl. ist spurlos verschwunden.
			03DEC2009	YES	10:00	YES	21:45	
			04DEC2009	YES	8:30	YES	22:00	
			05DEC2009	YES	8:30	YES	22:00	
			06DEC2009	YES	9:00	YES	22:15	
			07DEC2009	YES	9:15	YES	22:30	
			08DEC2009	YES	9:00	YES	22:00	
			09DEC2009	YES	9:30	YES	22:45	
			10DEC2009	YES	9:00	YES	22:00	
			11DEC2009	YES	9:00	YES	23:15	
			12DEC2009	YES	9:30	YES	22:15	
			13DEC2009	YES	9:45	YES	22:30	
			14DEC2009	YES	8:30	YES	22:30	
			15DEC2009	YES	10:00	YES	22:15	
			16DEC2009	YES	9:30	YES	22:00	
			17DEC2009	YES	9:45	YES	22:15	
			18DEC2009	YES	9:30	YES	22:15	
			19DEC2009	YES	9:30	YES	23:00	
			20DEC2009	YES	9:30	YES	22:30	
			21DEC2009	YES	8:30	YES	22:00	
			22DEC2009	YES	9:00	YES	22:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	23DEC2009	YES	9:30	YES	22:15	
			24DEC2009	YES	9:15	YES	23:00	
			25DEC2009	YES	10:00	YES	23:00	
			26DEC2009	YES	10:00	YES	23:15	
			27DEC2009	YES	10:15	YES	22:00	
			28DEC2009	YES	9:45	YES	22:15	
			29DEC2009	YES	10:00	YES	22:00	
			30DEC2009		9:45	YES	22:45	
			31DEC2009	YES	10:15	YES	23:00	
			01JAN2010	YES	10:15	YES	22:30	
			02JAN2010	YES	9:45	YES	22:45	
			03JAN2010	YES	10:00	YES	23:00	
			04JAN2010	YES	9:45	YES	22:30	
			05JAN2010	YES	9:15	YES	21:45	
			06JAN2010	YES	9:30	YES	21:45	
			07JAN2010	YES	9:30	YES	22:00	
			08JAN2010	YES	9:45	YES	22:00	
			09JAN2010		9:30		21:45	
			10JAN2010		9:15		21:45	
			11JAN2010		9:30		22:15	
			12JAN2010		9:45		22:00	
			13JAN2010		9:45		21:30	
			14JAN2010		9:15		21:15	
			15JAN2010		9:30		22:15	
			16JAN2010		9:00		22:30	

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	17JAN2010		9:30		22:00	
			18JAN2010		9:45		21:45	
			19JAN2010		9:45		21:30	
			20JAN2010		9:30		22:15	
			21JAN2010		8:30		21:15	
			22JAN2010		9:15		21:45	
			23JAN2010		8:45		22:00	
			24JAN2010		8:30		21:45	
			25JAN2010					Besuch bei Dr. Ackl 09:15
			25JAN2010	YES	12:00	YES	22:30	Bei Studie (Dr. Ackl) Morgentablette daher erst mittags.
			26JAN2010	YES	10:00	YES	22:00	
			27JAN2010	YES	9:45	YES	22:15	
			28JAN2010	YES	9:30	YES	21:45	
			29JAN2010	YES	10:00	YES	21:30	
			30JAN2010	YES	9:45	YES	22:00	
			31JAN2010	YES	9:30	YES	22:00	
			01FEB2010	YES	9:45	YES	21:50	
			02FEB2010	YES	9:30	YES	21:30	
			03FEB2010		8:30	YES	22:00	
			04FEB2010		8:45	YES	22:15	
			05FEB2010		9:00	YES	21:45	
			06FEB2010		9:15	YES	21:30	
			07FEB2010		9:30	YES	20:30	
			08FEB2010		8:45	YES	21:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	09FEB2010		8:45	YES	21:00	
			10FEB2010		9:00	YES	21:45	
			11FEB2010		9:15	YES	21:45	
			12FEB2010	YES	9:15	YES	22:00	
			13FEB2010	YES	8:45	YES	21:45	
			14FEB2010	YES	9:30	YES	22:00	
			15FEB2010	YES	8:30	YES	21:30	
			16FEB2010	YES	9:00	YES	22:15	
			17FEB2010	YES	9:15	YES	21:45	
			18FEB2010	YES	9:30	YES	21:30	
			19FEB2010	YES	9:45	YES	22:00	
			20FEB2010	YES	9:30	YES	22:15	
			21FEB2010	YES	9:00	YES	22:15	
			22FEB2010	YES	9:30	YES	21:45	
			23FEB2010	YES	8:45	YES	21:30	
			24FEB2010	YES	8:30	YES	21:45	
			25FEB2010	YES	9:45	YES	21:45	
			26FEB2010	YES	9:45	YES	22:15	
			27FEB2010	YES	9:30	YES	21:30	
			28FEB2010	YES	10:00	YES	22:15	
			01MAR2010	YES	9:45	YES	21:45	
			02MAR2010	YES	9:00	YES	21:30	
			04MAR2010	YES	9:15	YES	21:45	
			05MAR2010	YES	10:00	YES	22:00	
			06MAR2010	YES	9:30	YES	21:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	07MAR2010	YES	9:15	YES	22:15	
			08MAR2010	YES	9:30	YES	22:30	
			09MAR2010	YES	9:45	YES	21:45	
			10MAR2010	YES	8:45	YES	21:30	
			11MAR2010	YES	9:00	YES	22:00	
			12MAR2010	YES	8:30	YES	22:00	
			13MAR2010	YES	9:45	YES	22:15	
			14MAR2010	YES	9:15	YES	22:30	
			15MAR2010	YES	10:00	YES	21:45	
			16MAR2010	YES	10:15	YES	21:45	
			17MAR2010	YES	9:45	YES	22:00	
			18MAR2010	YES	9:45	YES	22:15	
			19MAR2010	YES	8:45	YES	22:30	
			20MAR2010	YES	9:30	YES	21:30	
			21MAR2010	YES	8:45	YES	22:00	
			22MAR2010	YES	8:30	YES	21:45	
			23MAR2010	YES	9:00	YES	21:30	
			24MAR2010	YES	9:15	YES	21:45	
			25MAR2010	YES	8:30	YES	22:15	
			26MAR2010	YES	8:45	YES	22:30	
			27MAR2010	YES	8:30	YES	22:45	
			28MAR2010	YES	9:30	YES	22:15	
			29MAR2010	YES		YES	21:45	
			30MAR2010	YES	9:00	YES	22:00	
			31MAR2010	YES	9:15	YES	22:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	01APR2010	YES	9:30	YES	21:45	
			02APR2010	YES	9:30	YES	21:30	
			03APR2010	YES	9:15	YES	21:45	
			05APR2010	YES	9:30	YES	22:00	
			06APR2010	YES	8:30	YES	22:00	
			07APR2010	YES	9:15	YES	22:15	
			08APR2010	YES	9:00	YES	21:45	
			09APR2010	YES	8:45	YES	21:45	
			10APR2010	YES	9:15	YES	22:45	
			11APR2010	YES	9:30	YES	22:00	
			12APR2010	YES	10:00	YES	21:45	
			13APR2010	YES	9:15	YES	21:45	
			14APR2010	YES	10:15	YES	21:45	
			15APR2010	YES	10:00	YES	22:00	
			16APR2010	YES	9:45	YES	21:30	
			17APR2010	YES	9:15	YES	22:15	
			18APR2010	YES	8:45	YES	21:45	
			19APR2010	YES	9:15	YES	22:00	
			20APR2010	YES	9:30	YES	21:45	
			21APR2010	YES	9:30	YES	22:00	
			22APR2010	YES	10:00			Besuch bei Frau Dr. Ackl.
			22APR2010			YES	21:15	Uhrzeiten sind +- wie bei Besuch 3 und auf dieser Seite. Fahrkostenpauschale, die ich dafür erhalte, wiegen den Zeitaufwand nicht auf!
			23APR2010	YES	8:00	YES	21:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	24APR2010	YES	8:00	YES	21:00	
			25APR2010	YES	8:00	YES	21:00	
			26APR2010	YES	8:00	YES	21:15	
			27APR2010	YES	8:00	YES	21:30	
			28APR2010	YES	9:15	YES	22:15	
			29APR2010	YES	9:30	YES	22:00	
			30APR2010	YES	9:15	YES	21:45	
			01MAY2010	YES		YES		
			02MAY2010	YES		YES		
			03MAY2010	YES		YES		
			04MAY2010	YES		YES		
			05MAY2010	YES		YES		
			06MAY2010	YES		YES		
			07MAY2010	YES		YES		
			08MAY2010	YES		YES		
			09MAY2010	YES		YES		
			10MAY2010	YES		YES		
			11MAY2010	YES		YES		
			12MAY2010	YES		YES		
			13MAY2010	YES		YES		
			14MAY2010	YES		YES		
			15MAY2010	YES		YES		
			16MAY2010	YES		YES		
			17MAY2010	YES		YES		
			18MAY2010	YES		YES		

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	19MAY2010	YES		YES		
			20MAY2010	YES		YES		
			21MAY2010	YES		YES		
			22MAY2010	YES		YES		
			23MAY2010	YES		YES		
			24MAY2010	YES		YES		
			25MAY2010	YES		YES		
			26MAY2010	YES		YES		
			27MAY2010	YES		YES		
			28MAY2010	YES		YES		
			29MAY2010	YES		YES		
			30MAY2010	YES		YES		
			31MAY2010	YES		YES		
			01JUN2010	YES		YES		
			02JUN2010	YES		YES		
			03JUN2010	YES		YES		
			04JUN2010	YES		YES		
			05JUN2010	YES		YES		
			06JUN2010	YES		YES		
			07JUN2010	YES		YES		
			08JUN2010	YES		YES		
			09JUN2010	YES		YES		
			10JUN2010	YES		YES		
			11JUN2010	YES		YES		
			12JUN2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	13JUN2010	YES		YES		
			14JUN2010	YES		YES		
			15JUN2010	YES		YES		
			16JUN2010	YES		YES		
			17JUN2010	YES		YES		
			18JUN2010	YES		YES		
			19JUN2010	YES		YES		
			20JUN2010	YES		YES		
			21JUN2010	YES		YES		
			22JUN2010	YES		YES		
			23JUN2010	YES		YES		
			24JUN2010	YES		YES		
			25JUN2010	YES		YES		
			26JUN2010	YES		YES		
			27JUN2010	YES		YES		
			28JUN2010	YES		YES		
			29JUN2010	YES		YES		
			30JUN2010	YES		YES		
			01JUL2010	YES		YES		
			02JUL2010	YES		YES		
			03JUL2010	YES		YES		
			04JUL2010	YES		YES		
			05JUL2010	YES		YES		
			06JUL2010	YES		YES		
			07JUL2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	08JUL2010	YES		YES		
			09JUL2010	YES		YES		
			10JUL2010	YES		YES		
			11JUL2010	YES		YES		
			12JUL2010	YES		YES		
			13JUL2010	YES		YES		
			14JUL2010	YES		YES		
			15JUL2010	YES				
			15JUL2010			YES		Vormittag in Kl. Großh. - bei Dr. Ackl
			16JUL2010	YES		YES		
			17JUL2010	YES		YES		
			18JUL2010	YES		YES		
			19JUL2010	YES		YES		
			20JUL2010	YES		YES		
			21JUL2010	YES		YES		
			23JUL2010	YES		YES		
			24JUL2010	YES		YES		
			25JUL2010	YES		YES		
			26JUL2010	YES		YES		
			27JUL2010	YES		YES		
			28JUL2010	YES		YES		
			29JUL2010	YES		YES		
			30JUL2010	YES		YES		
			31JUL2010	YES		YES		
			01AUG2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	02AUG2010	YES		YES		
			03AUG2010	YES		YES		
			04AUG2010	YES		YES		
			05AUG2010	YES		YES		
			06AUG2010	YES		YES		
			07AUG2010	YES		YES		
			08AUG2010	YES		YES		
			09AUG2010	YES		YES		
			10AUG2010	YES		YES		
			11AUG2010	YES		YES		
			12AUG2010	YES		YES		
			13AUG2010	YES		YES		
			14AUG2010	YES		YES		
			15AUG2010	YES		YES		
			16AUG2010	YES		YES		
			17AUG2010	YES		YES		
			18AUG2010	YES		YES		
			19AUG2010	YES		YES		
			20AUG2010	YES		YES		
			21AUG2010	YES		YES		
			22AUG2010	YES		YES		
			23AUG2010	YES		YES		
			24AUG2010	YES		YES		
			25AUG2010	YES		YES		
			26AUG2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	27AUG2010	YES		YES		
			28AUG2010	YES		YES		
			30AUG2010	YES				Noch Pille verabreicht
			31AUG2010					Für richtige Einnahme keine Garantie, da ich bis einschl. 07.09.2010 nicht bei meinem Mann war.
			01SEP2010					Für richtige Einnahme keine Garantie, da ich bis einschl. 07.09.2010 nicht bei meinem Mann war.
			02SEP2010					Für richtige Einnahme keine Garantie, da ich bis einschl. 07.09.2010 nicht bei meinem Mann war.
			03SEP2010					Für richtige Einnahme keine Garantie, da ich bis einschl. 07.09.2010 nicht bei meinem Mann war.
			04SEP2010					Für richtige Einnahme keine Garantie, da ich bis einschl. 07.09.2010 nicht bei meinem Mann war.
			05SEP2010					Für richtige Einnahme keine Garantie, da ich bis einschl. 07.09.2010 nicht bei meinem Mann war.
			06SEP2010					Für richtige Einnahme keine Garantie, da ich bis einschl. 07.09.2010 nicht bei meinem Mann war.
			07SEP2010	YES		YES		siehe <-, Pille verabr.
			08SEP2010	YES		YES		
			09SEP2010	YES		YES		
			10SEP2010	YES		YES		
			11SEP2010	YES		YES		
			12SEP2010	YES		YES		
			13SEP2010	YES		YES		
			14SEP2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	15SEP2010	YES		YES		
			16SEP2010	YES		YES		
			17SEP2010	YES		YES		
			18SEP2010	YES		YES		
			19SEP2010	YES		YES		
			20SEP2010	YES		YES		
			21SEP2010	YES		YES		
			22SEP2010	YES		YES		
			23SEP2010	YES		YES		
			24SEP2010	YES		YES		
			25SEP2010	YES		YES		
			26SEP2010	YES		YES		
			27SEP2010	YES		YES		
			28SEP2010	YES		YES		
			29SEP2010	YES		YES		
			01OCT2010	YES		YES		
			02OCT2010	YES		YES		
			03OCT2010	YES		YES		
			04OCT2010	YES		YES		
			05OCT2010	YES		YES		
			06OCT2010	YES		YES		
			07OCT2010	YES		YES		
			08OCT2010	YES		YES		
			09OCT2010	YES		YES		
			10OCT2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	014	4	11OCT2010	YES		YES		
			12OCT2010	YES		YES		
			13OCT2010	YES		YES		
			14OCT2010	YES		YES		
			15OCT2010	YES		YES		
			16OCT2010	YES		YES		
			17OCT2010	YES		YES		
			18OCT2010	YES		YES		
			19OCT2010	YES		YES		
			20OCT2010	YES		YES		
			21OCT2010	YES		YES		
			22OCT2010	YES		YES		
			23OCT2010	YES		YES		
			24OCT2010	YES		YES		
			25OCT2010	YES		YES		
			26OCT2010	YES		YES		
			27OCT2010	YES		YES		
			28OCT2010	YES				
	015	4	22FEB2010	YES	13:00	YES	18:50	
			23FEB2010	YES	7:30	YES	18:30	
			24FEB2010	YES	7:30	YES	18:30	
			25FEB2010	YES	7:30	YES	18:35	
			26FEB2010	YES	7:35	YES	18:30	
			27FEB2010	YES	7:00	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	28FEB2010	YES	7:30	YES	18:30	
			01MAR2010	YES	7:30	YES	18:15	
			02MAR2010	YES	7:30	YES	18:25	
			03MAR2010	YES	7:35	YES	18:20	
			04MAR2010	YES	7:30	YES	18:00	
			05MAR2010	YES	7:30	YES	18:30	
			06MAR2010	YES	7:30	YES	18:45	
			07MAR2010	YES	7:30	YES	18:05	
			08MAR2010	YES	7:30	YES	18:50	
			09MAR2010	YES	7:30	YES	18:30	
			10MAR2010	YES	7:30	YES	18:00	
			11MAR2010	YES	7:30	YES	18:30	
			12MAR2010	YES	7:30	YES	19:00	
			13MAR2010	YES	7:00	YES	18:30	
			14MAR2010	YES	7:30	YES	18:30	
			15MAR2010	YES	7:30	YES	18:30	
			16MAR2010	YES	7:30	YES	18:40	
			17MAR2010	YES	7:40	YES	18:20	
			18MAR2010	YES	7:30	YES	18:30	
			19MAR2010	YES	7:30	YES	18:30	
			20MAR2010	YES	7:30	YES	18:30	
			21MAR2010	YES	7:30	YES	18:50	
			22MAR2010	YES	7:30			
			22MAR2010			YES	18:00	
			23MAR2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	24MAR2010	YES	7:30	YES	18:45	
			25MAR2010	YES	7:35	YES	18:30	
			26MAR2010	YES	7:40	YES	18:30	
			27MAR2010	YES	7:30	YES	18:30	
			28MAR2010	YES	8:30	YES	18:50	
			29MAR2010	YES	7:30	YES	18:30	
			30MAR2010	YES	7:30	YES	18:30	
			31MAR2010	YES	7:30	YES	19:00	
			01APR2010	YES	7:35	YES	18:30	
			02APR2010	YES	7:30	YES	18:30	
			03APR2010	YES	7:30	YES	18:30	
			04APR2010	YES	7:30	YES	18:30	
			05APR2010	YES	7:30	YES	18:45	
			06APR2010	YES	7:20	YES	18:30	
			07APR2010	YES	7:30	YES	18:30	
			08APR2010	YES	7:30	YES	18:30	
			09APR2010	YES	7:30	YES	19:00	
			10APR2010	YES	7:30	YES	18:30	
			11APR2010	YES	7:35	YES	18:30	
			12APR2010	YES	7:30	YES	18:35	
			13APR2010	YES	7:30	YES	18:20	
			14APR2010	YES	7:40	YES	18:30	
			15APR2010	YES	7:30	YES	18:30	
			16APR2010	YES	7:30	YES	18:30	
			17APR2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	18APR2010	YES	7:30	YES	18:00	
			19APR2010	YES	7:40	YES	18:30	
			20APR2010	YES	7:35	YES	18:45	
			21APR2010	YES	7:40	YES	18:30	
			22APR2010	YES	7:30	YES	18:30	
			23APR2010	YES	7:40	YES	18:40	
			24APR2010	YES	7:30	YES	18:35	
			25APR2010	YES	7:40	YES	18:30	
			26APR2010	YES	7:30	YES	18:30	
			27APR2010	YES	7:30	YES	18:45	
			28APR2010	YES	7:30	YES	18:30	
			29APR2010	YES	7:40	YES	18:30	
			30APR2010	YES	7:50	YES	18:40	
			01MAY2010	YES	7:30	YES	18:35	
			02MAY2010	YES	7:30	YES	18:40	
			03MAY2010	YES	7:35	YES	18:40	
			04MAY2010	YES	7:30	YES	18:30	
			05MAY2010	YES	7:30	YES	18:30	
			06MAY2010	YES	7:30	YES	18:30	
			07MAY2010	YES	7:30	YES	18:30	
			08MAY2010	YES	7:30	YES	18:15	
			09MAY2010	YES	7:35	YES	18:25	
			10MAY2010	YES	8:00	YES	18:30	
			11MAY2010	YES	7:30	YES	18:30	
			12MAY2010	YES	7:40	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	13MAY2010	YES	7:30	YES	18:30	
			14MAY2010	YES	7:30	YES	18:30	
			15MAY2010	YES	7:30	YES	18:15	
			16MAY2010	YES	7:30	YES	18:30	
			17MAY2010	YES	7:15			
			17MAY2010			YES	18:20	
			18MAY2010	YES	7:30	YES	18:00	
			19MAY2010	YES	7:20	YES	18:00	
			20MAY2010	YES	7:30	YES	18:20	
			21MAY2010	YES	7:30	YES	18:30	
			22MAY2010	YES	6:40	YES	18:30	
			23MAY2010	YES	7:30	YES	18:30	
			24MAY2010	YES	7:30	YES	18:00	
			25MAY2010	YES	7:30	YES	18:00	
			26MAY2010	YES	8:00	YES	18:00	
			27MAY2010	YES	7:40	YES	18:10	
			28MAY2010	YES	7:30	YES	18:10	
			29MAY2010	YES	7:30	YES	18:10	
			30MAY2010	YES	7:30	YES	18:30	
			31MAY2010	YES	7:30	YES	18:30	
			01JUN2010	YES	7:30	YES	18:30	
			02JUN2010	YES	7:20	YES	18:20	
			03JUN2010	YES	7:40	YES	18:20	
			04JUN2010	YES	7:30	YES	18:00	
			05JUN2010	YES	7:30	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	06JUN2010	YES	7:30	YES	18:30	
			07JUN2010	YES	7:25	YES	18:30	
			08JUN2010	YES	7:30	YES	18:30	
			09JUN2010	YES	7:10	YES	18:30	
			10JUN2010	YES	7:15	YES	18:30	
			11JUN2010	YES	7:30	YES	18:30	
			12JUN2010	YES	7:00	YES	18:00	
			13JUN2010	YES	7:30	YES	18:10	
			14JUN2010	YES	7:30	YES	18:15	
			15JUN2010	YES	7:20	YES	18:30	
			16JUN2010	YES	7:20	YES	18:30	
			17JUN2010	YES	7:30	YES	18:45	
			18JUN2010	YES	7:45	YES	19:00	
			19JUN2010	YES	6:30	YES	18:30	
			20JUN2010	YES	7:30	YES	18:30	
			21JUN2010	YES	7:30	YES	18:30	
			22JUN2010	YES	8:00	YES	18:45	
			23JUN2010	YES	7:30	YES	18:30	
			24JUN2010	YES	8:30	YES	18:30	
			25JUN2010	YES	7:30	YES	19:00	
			26JUN2010	YES	6:50	YES	19:00	
			27JUN2010	YES	7:30	YES	18:30	
			28JUN2010	YES	7:30	YES	18:30	
			29JUN2010	YES	7:30	YES	18:30	
			30JUN2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	01JUL2010	YES	7:30	YES	18:20	
			02JUL2010	YES	7:30	YES	18:30	
			03JUL2010	YES	6:20	YES	18:30	
			04JUL2010	YES	7:30	YES	18:00	
			05JUL2010	YES	7:30	YES	18:00	
			06JUL2010	YES	7:20	YES	18:00	
			07JUL2010	YES	7:15	YES	18:00	
			08JUL2010	YES	7:30	YES	18:00	
			09JUL2010	YES	7:30	YES	18:00	
			10JUL2010	YES	7:30	YES	18:00	
			11JUL2010	YES	7:30	YES	18:30	
			12JUL2010	YES	7:30	YES	18:30	
			13JUL2010	YES	8:00	YES	19:00	
			14JUL2010	YES	7:30	YES	18:30	
			15JUL2010	YES	7:30	YES	18:30	
			16JUL2010	YES	7:30	YES	18:30	
			17JUL2010	YES	7:45	YES	18:30	
			18JUL2010	YES	7:30	YES	18:30	
			19JUL2010	YES	7:30	YES	18:30	
			20JUL2010	YES	7:30	YES	18:30	
			21JUL2010	YES	7:30	YES	18:00	
			22JUL2010	YES	7:00	YES	18:30	
			23JUL2010	YES	7:30	YES	18:00	
			24JUL2010	YES	7:30	YES	18:30	
			25JUL2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	26JUL2010	YES	7:30	YES	18:30	
			27JUL2010	YES	7:30	YES	18:30	
			28JUL2010	YES	7:30	YES	18:30	
			29JUL2010	YES	7:30	YES	18:30	
			30JUL2010	YES	7:30	YES	18:30	
			31JUL2010	YES	7:30	YES	18:30	
			01AUG2010	YES	7:30	YES	18:30	
			02AUG2010	YES	7:30			
			02AUG2010		8:00	YES	18:00	
			03AUG2010	YES	8:00	YES	18:00	
			04AUG2010	YES	8:00	YES	18:30	
			05AUG2010	YES	8:15	YES	18:30	
			06AUG2010	YES	8:00	YES	18:30	
			07AUG2010	YES	8:00	YES	18:00	
			08AUG2010	YES	7:30	YES	18:00	
			09AUG2010	YES	8:00	YES	18:30	
			10AUG2010	YES	8:00	YES	18:30	
			11AUG2010	YES	7:45	YES	18:00	
			12AUG2010	YES	8:00	YES	18:30	
			13AUG2010	YES	8:00	YES	18:30	
			14AUG2010	YES	8:00	YES	18:30	
			15AUG2010	YES	7:30	YES	18:00	
			16AUG2010	YES	8:00	YES	18:30	
			17AUG2010	YES	8:00	YES	18:30	
			18AUG2010	YES	8:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	19AUG2010	YES	8:00	YES	18:30	
			20AUG2010	YES	7:45	YES	18:00	
			21AUG2010	YES	7:45	YES	18:00	
			22AUG2010	YES	8:00	YES	18:30	
			23AUG2010	YES	8:00	YES	18:15	
			24AUG2010	YES	8:00	YES	18:15	
			25AUG2010	YES	7:30	YES	18:00	
			26AUG2010	YES	7:30	YES	18:00	
			27AUG2010	YES	7:30	YES	18:15	
			28AUG2010	YES	7:45	YES	18:15	
			29AUG2010	YES	8:00	YES	18:00	
			30AUG2010	YES	7:30	YES	18:30	
			31AUG2010	YES	7:30	YES	18:00	
			01SEP2010	YES	7:30	YES	18:00	
			02SEP2010	YES	7:30	YES	18:30	
			03SEP2010	YES	7:45	YES	18:30	
			04SEP2010	YES	7:30	YES	18:30	
			05SEP2010	YES	8:00	YES	18:00	
			06SEP2010	YES	8:00	YES	18:15	
			07SEP2010	YES	7:30	YES	17:00	
			08SEP2010	YES	7:30	YES	18:00	
			09SEP2010	YES	7:45	YES	18:00	
			10SEP2010	YES	7:30	YES	18:30	
			11SEP2010	YES	7:45	YES	18:00	
			12SEP2010	YES	7:30	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	13SEP2010	YES	7:30	YES	18:15	
			14SEP2010	YES	7:30	YES	18:30	
			15SEP2010	YES	8:00	YES	18:30	
			16SEP2010	YES	8:00	YES	18:00	
			17SEP2010	YES	8:00	YES	18:15	
			18SEP2010	YES	7:30	YES	18:15	
			19SEP2010	YES	7:30	YES	18:00	
			20SEP2010	YES	7:30	YES	18:00	
			21SEP2010	YES	7:45	YES	18:30	
			22SEP2010	YES	7:30	YES	18:30	
			23SEP2010	YES	7:45	YES	18:30	
			24SEP2010	YES	7:30	YES	18:45	
			25SEP2010	YES	8:00	YES	17:30	
			26SEP2010	YES	7:45	YES	17:45	
			27SEP2010	YES	8:00	YES	18:00	
			28SEP2010	YES	7:30	YES	18:15	
			29SEP2010	YES	7:30	YES	18:00	
			30SEP2010	YES	7:30	YES	18:30	
			01OCT2010	YES	7:30	YES	18:30	
			02OCT2010	YES	7:45	YES	18:15	
			03OCT2010	YES	7:30	YES	18:00	
			04OCT2010	YES	7:45	YES	18:00	
			05OCT2010	YES	7:30	YES	18:00	
			06OCT2010	YES	7:30	YES	18:15	
			07OCT2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	08OCT2010	YES	8:00	YES	18:30	
			09OCT2010	YES	7:45	YES	18:30	
			10OCT2010	YES	7:45	YES	18:15	
			11OCT2010	YES	7:30	YES	18:15	
			12OCT2010	YES	7:30	YES	18:30	
			13OCT2010	YES	7:45	YES	18:00	
			14OCT2010	YES	7:45	YES	18:00	
			15OCT2010	YES	7:30	YES	18:15	
			16OCT2010	YES	7:30	YES	18:30	
			17OCT2010	YES	7:30	YES	18:30	
			18OCT2010	YES	7:30	YES	18:30	
			19OCT2010	YES	7:45	YES	18:00	
			20OCT2010	YES	7:45	YES	18:15	
			21OCT2010	YES	7:30	YES	18:30	
			22OCT2010	YES	7:45	YES	18:15	
			23OCT2010	YES	7:30	YES	18:00	
			24OCT2010	YES	7:30	YES	18:30	
			25OCT2010	YES	7:45	YES	18:30	
			26OCT2010	YES	7:45	YES	18:15	
			27OCT2010	YES	7:30			
			27OCT2010			YES	18:00	
			28OCT2010	YES	8:30	YES	19:00	
			30OCT2010	YES	7:30	YES	18:45	
			31OCT2010	YES	7:30	YES	19:00	
			01NOV2010	YES	8:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	02NOV2010	YES	7:30	YES	18:00	
			03NOV2010	YES	7:30	YES	18:30	
			04NOV2010	YES	7:30	YES	18:30	
			05NOV2010	YES	7:45	YES	18:30	
			06NOV2010	YES	7:30	YES	18:30	
			07NOV2010	YES	7:30	YES	18:30	
			08NOV2010	YES	7:45	YES	18:45	
			09NOV2010	YES	7:30	YES	18:30	
			10NOV2010	YES	7:30	YES	18:30	
			11NOV2010	YES	7:30	YES	18:45	
			12NOV2010	YES	7:45	YES	18:45	
			13NOV2010	YES	7:30	YES	18:30	
			14NOV2010	YES	7:30	YES	18:30	
			15NOV2010	YES	7:30	YES	18:15	
			16NOV2010	YES	7:40	YES	18:30	
			17NOV2010	YES	7:30	YES	18:30	
			18NOV2010	YES	7:45	YES	18:30	
			19NOV2010	YES	7:45	YES	19:00	
			20NOV2010	YES	7:30	YES	18:30	
			21NOV2010	YES	7:30	YES	18:30	
			22NOV2010	YES	7:30	YES	18:30	
			23NOV2010	YES	7:30	YES	18:30	
			24NOV2010	YES	7:45	YES	18:30	
			25NOV2010	YES	7:30	YES	18:00	
			26NOV2010	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	27NOV2010	YES	7:30	YES	18:30	
			28NOV2010	YES	8:00	YES	18:30	
			29NOV2010	YES	7:30	YES	18:30	
			30NOV2010	YES	7:30	YES	18:30	
			01DEC2010	YES	7:40	YES	18:30	
			02DEC2010	YES	7:30	YES	18:30	
			03DEC2010	YES	7:30	YES	18:00	
			04DEC2010	YES	7:40	YES	18:30	
			05DEC2010	YES	7:30	YES	18:30	
			06DEC2010	YES	7:30	YES	18:30	
			07DEC2010	YES	7:30	YES	18:15	
			08DEC2010	YES	7:30	YES	18:30	
			09DEC2010	YES	7:30	YES	18:30	
			10DEC2010	YES	7:40	YES	18:15	
			11DEC2010	YES	7:30	YES	18:30	
			12DEC2010	YES	7:30	YES	18:30	
			13DEC2010	YES	7:30	YES	18:30	
			14DEC2010	YES	7:30	YES	18:00	
			15DEC2010	YES	7:45	YES	18:30	
			16DEC2010	YES	7:30	YES	18:45	
			17DEC2010	YES	7:30	YES	19:00	
			18DEC2010	YES	7:30	YES	18:30	
			19DEC2010	YES	7:30	YES	18:30	
			20DEC2010	YES	7:30	YES	18:30	
			21DEC2010	YES	7:30	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	22DEC2010	YES	7:30	YES	18:30	
			23DEC2010	YES	7:40	YES	18:30	
			24DEC2010	YES	7:30	YES	18:45	
			25DEC2010	YES	8:00	YES	18:30	
			26DEC2010	YES	8:00	YES	18:30	
			27DEC2010	YES	7:30	YES	18:30	
			28DEC2010	YES		YES		
			29DEC2010	YES	7:30	YES	19:00	
			29DEC2010	YES		YES		
			30DEC2010	YES		YES		
			31DEC2010	YES	7:30	YES	18:00	
			01JAN2011	YES	9:00	YES	18:30	
			02JAN2011	YES	7:45	YES	18:30	
			03JAN2011	YES	7:30	YES	18:30	
			04JAN2011	YES	7:30	YES	18:30	
			05JAN2011	YES	7:30	YES	18:30	
			06JAN2011	YES	7:30	YES	18:15	
			07JAN2011	YES	7:30	YES	18:15	
			08JAN2011	YES	7:30	YES	18:30	
			09JAN2011	YES	7:45	YES	18:30	
			10JAN2011	YES	7:30	YES	18:30	
			11JAN2011	YES	7:30	YES	18:30	
			12JAN2011	YES	7:30	YES	18:30	
			13JAN2011	YES	7:30	YES	18:30	
			14JAN2011	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	15JAN2011	YES	7:30	YES	18:00	
			16JAN2011	YES	7:30	YES	18:30	
			17JAN2011	YES	7:45	YES	18:30	
			18JAN2011	YES	7:50	YES	18:30	
			19JAN2011	YES	7:30	YES	18:30	
			20JAN2011	YES	7:30	YES	18:15	
			21JAN2011	YES	7:30	YES	18:15	
			22JAN2011	YES	7:30	YES	18:30	
			23JAN2011	YES	7:30	YES	18:30	
			24JAN2011	YES	7:30	YES	18:30	
			25JAN2011	YES	7:30	YES	18:30	
			26JAN2011	YES	7:30	YES	18:20	
			27JAN2011	YES	7:30	YES	18:30	
			28JAN2011	YES	7:45	YES	18:15	
			29JAN2011	YES	7:40	YES	18:20	
			30JAN2011	YES	7:30	YES	18:30	
			31JAN2011	YES	7:30	YES	18:30	
			01FEB2011	YES	7:30	YES	18:30	
			02FEB2011	YES	7:30	YES	18:30	
			03FEB2011	YES	7:30	YES	18:30	
			04FEB2011	YES	7:40	YES	18:30	
			05FEB2011	YES	7:30	YES	18:30	
			06FEB2011	YES	7:30	YES	18:30	
			07FEB2011	YES	7:30	YES	18:30	
			08FEB2011	YES	7:30	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	015	4	09FEB2011	YES	7:30	YES	18:30	
			10FEB2011	YES	7:30	YES	18:30	
			11FEB2011	YES	7:30	YES	18:30	
			12FEB2011	YES	7:40	YES	18:30	
			13FEB2011	YES	7:30	YES	18:30	
			14FEB2011	YES	7:30	YES	18:45	
			15FEB2011	YES	7:30	YES	18:30	
			16FEB2011	YES	7:30	YES	18:30	
			17FEB2011	YES	7:15	YES	18:30	
			18FEB2011	YES	7:30	YES	18:30	
			19FEB2011	YES	7:30	YES	18:30	
			20FEB2011	YES	7:30	YES	18:15	
			21FEB2011	YES	7:00			
	017	5	06AUG2009	YES	7:15	YES	18:45	
			07AUG2009	YES	7:00	YES	19:15	
			08AUG2009	YES	9:00	YES	19:45	
			09AUG2009	YES	8:00	YES	21:00	
			10AUG2009	YES	7:10	YES	18:45	
			11AUG2009	YES	8:00	YES	18:45	
			12AUG2009	YES	7:15	YES	18:50	
			13AUG2009	YES	7:20	YES	19:00	
			14AUG2009	YES	7:30	YES	19:00	
			15AUG2009	YES	8:30	YES	18:30	
			16AUG2009	YES	7:50	YES	19:00	

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	17AUG2009	YES	7:15	YES	19:10	
			18AUG2009	YES	7:00	YES	19:00	
			19AUG2009	YES	7:30	YES	19:00	
			20AUG2009	YES	7:00	YES	19:45	
			21AUG2009	YES	7:15	YES	19:00	
			22AUG2009	YES	7:40	YES	20:10	
			23AUG2009	YES	7:30	YES	19:00	
			24AUG2009	YES	7:40	YES	19:00	
			25AUG2009	YES	7:10	YES	19:00	
			26AUG2009	YES	7:30	YES	19:00	
			27AUG2009	YES	7:30	YES	18:45	
			28AUG2009	YES	7:15	YES	18:45	
			29AUG2009	YES	7:30	YES	18:45	
			30AUG2009	YES	7:45	YES	18:45	
			31AUG2009	YES	7:00	YES	18:45	
			01SEP2009	YES	7:30	YES	18:45	
			02SEP2009	YES	7:00			
			02SEP2009	YES	7:00	YES	19:30	
			03SEP2009	YES	7:30	YES	18:45	
			04SEP2009	YES	7:00	YES	18:45	
			05SEP2009	YES	7:45	YES	18:45	
			06SEP2009	YES	7:45	YES	18:45	
			07SEP2009	YES	7:30	YES	18:45	
			08SEP2009	YES	7:30	YES	18:45	
			09SEP2009	YES	7:30	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	10SEP2009	YES	7:30	YES	19:45	
			11SEP2009	YES	7:45	YES	18:30	
			12SEP2009	YES	7:30	YES	18:45	
			13SEP2009	YES	7:45	YES	18:45	
			14SEP2009	YES	12:30	YES	19:15	Arztbesuch: Gesundheitscheck beim Hausarzt
			15SEP2009	YES	7:45	YES	18:45	
			16SEP2009	YES	7:30	YES	18:45	
			17SEP2009	YES	7:30	YES	18:45	
			18SEP2009	YES	7:15	YES	18:45	
			19SEP2009	YES	7:00	YES	18:45	
			20SEP2009	YES	8:30	YES	18:45	
			21SEP2009	YES	7:30	YES	18:45	
			22SEP2009	YES	8:00	YES	18:45	
			23SEP2009	YES	7:10	YES	18:45	
			24SEP2009	YES	7:30	YES	18:45	
			25SEP2009		7:30	YES	18:45	
			26SEP2009	YES	7:45	YES	19:45	
			27SEP2009	YES	7:45	YES	18:45	
			28SEP2009	YES	7:45	YES	18:45	
			29SEP2009	YES	7:45	YES	18:45	
			30SEP2009	YES	8:00	YES	18:45	
			01OCT2009	YES	7:30	YES	18:45	
			02OCT2009	YES	7:30	YES	18:45	
			03OCT2009	YES	8:00	YES	18:45	
			04OCT2009	YES	7:45	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	05OCT2009	YES	8:00	YES	19:15	
			06OCT2009	YES	7:45	YES	18:45	
			07OCT2009	YES	8:10	YES	19:15	
			08OCT2009	YES	8:45	YES	18:45	
			09OCT2009	YES	8:45	YES	18:00	
			10OCT2009	YES	8:00	YES	19:00	
			11OCT2009	YES	7:45	YES	19:00	
			12OCT2009	YES	7:45	YES	18:45	
			13OCT2009	YES	8:00	YES	19:00	
			14OCT2009	YES	8:00	YES	18:45	
			15OCT2009	YES	7:30	YES	19:00	
			16OCT2009	YES	8:00	YES	18:45	
			17OCT2009	YES	8:00	YES	19:00	
			18OCT2009	YES	9:00	YES	18:45	
			19OCT2009	YES	7:15	YES	18:45	
			20OCT2009		7:30	YES	18:45	
			21OCT2009	YES	8:00	YES	18:45	
			22OCT2009	YES	8:00	YES	18:45	
			23OCT2009	YES	8:00	YES	18:45	
			24OCT2009	YES	7:45	YES	18:45	
			25OCT2009	YES	8:00	YES	18:45	
			26OCT2009	YES	8:45	YES	18:45	
			27OCT2009	YES	7:30	YES	18:45	
			28OCT2009	YES	7:00			
			28OCT2009	YES	7:00	YES	18:45	Tab.-Einnahme, weil Besuch in Charité

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	29OCT2009	YES	7:45	YES	18:45	
			30OCT2009	YES	7:45	YES	18:45	
			31OCT2009	YES	7:45	YES	18:45	
			01NOV2009	YES	7:45	YES	18:45	
			02NOV2009	YES	7:45	YES	18:45	
			03NOV2009	YES	7:45	YES	18:45	
			04NOV2009	YES	7:30	YES	18:45	
			05NOV2009	YES	7:45	YES	18:45	
			06NOV2009	YES	7:45	YES	18:45	
			07NOV2009	YES	8:00	YES	18:45	
			08NOV2009	YES	8:00	YES	19:00	
			09NOV2009	YES	8:00	YES	18:45	
			10NOV2009	YES	8:00	YES	18:45	
			11NOV2009	YES	7:30	YES	18:45	
			12NOV2009	YES	7:30	YES	18:45	
			13NOV2009	YES	7:45	YES	18:45	
			14NOV2009	YES	7:45	YES	18:45	
			15NOV2009	YES	8:30	YES	18:45	
			16NOV2009	YES	8:45	YES	18:45	
			17NOV2009	YES	8:45	YES	18:45	
			18NOV2009	YES	7:15	YES	18:45	
			19NOV2009	YES	8:00	YES	18:45	
			20NOV2009	YES	7:45	YES	18:45	
			21NOV2009	YES	7:45	YES	18:45	
			22NOV2009	YES	8:00	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	23NOV2009	YES	7:45	YES	18:45	
			24NOV2009	YES	7:45	YES	18:45	
			25NOV2009	YES	7:45	YES	19:00	
			26NOV2009	YES	7:30	YES	18:45	
			27NOV2009	YES	7:30	YES	18:45	
			28NOV2009	YES	8:15	YES	18:45	
			29NOV2009	YES	8:15	YES	18:45	
			30NOV2009	YES	7:45	YES	18:45	
			01DEC2009	YES	7:45	YES	18:45	
			02DEC2009	YES	7:30	YES	18:45	
			03DEC2009	YES	7:30	YES	18:45	
			04DEC2009	YES	7:30	YES	18:45	
			05DEC2009	YES	7:30	YES	18:45	
			06DEC2009	YES	7:45	YES	19:15	
			07DEC2009	YES	7:45	YES	19:00	
			08DEC2009	YES	7:00	YES	18:45	
			09DEC2009	YES	7:45	YES	18:45	
			10DEC2009	YES	7:45	YES	18:45	
			11DEC2009	YES	7:45	YES	18:45	
			12DEC2009	YES	7:45	YES	19:15	
			13DEC2009	YES	8:00	YES	18:45	
			14DEC2009	YES	7:45	YES	18:45	
			15DEC2009	YES	8:00	YES	18:45	
			16DEC2009	YES	7:30	YES	18:45	
			17DEC2009	YES	7:15	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	18DEC2009	YES	7:45	YES	18:45	
			19DEC2009	YES	7:45	YES	18:45	
			20DEC2009	YES	7:45	YES	18:45	abends: nach 15 Min. ausgebrochen, keine Einnahme zum späteren Zeitpunkt
			21DEC2009	YES	7:15	NO		morgens nach 15 Min. ausgebrochen, abends nach Absprache mit Dr. Peters keine Einnahme
			22DEC2009	NO		NO		morgens keine Einnahme, abends keine Einnahme
			23DEC2009	NO		NO		auch keine Einnahme nach Absprache mit Dr. Peters
			24DEC2009	YES	8:00	YES	19:30	
			25DEC2009	YES	7:45	YES	18:45	
			26DEC2009	YES	8:00	YES	18:45	
			27DEC2009	YES	7:45	YES	19:30	
			28DEC2009	YES	7:45	YES	18:45	
			29DEC2009	YES	8:00	YES	18:45	
			30DEC2009	YES	8:00	YES	18:45	
			31DEC2009	YES	8:00	YES	19:30	
			01JAN2010	YES	8:45	YES	18:45	
			02JAN2010	YES	8:00	YES	18:45	
			03JAN2010	YES	8:00	YES	18:45	
			04JAN2010	YES	7:00	YES	18:45	
			05JAN2010	YES	7:45	YES	19:00	
			06JAN2010	YES	7:15	YES	18:45	
			07JAN2010	YES	7:45	YES	18:45	
			08JAN2010	YES	7:45	YES	19:00	
			09JAN2010	YES	8:00	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	10JAN2010	YES	8:00	YES	18:45	
			11JAN2010	YES	7:45	YES	18:45	
			12JAN2010	YES	8:00	YES	18:45	
			13JAN2010	YES	7:45	YES	18:45	
			14JAN2010	YES	8:00	YES	18:45	
			15JAN2010	YES	8:00	YES	18:45	
			16JAN2010	YES	8:00	YES	18:45	
			17JAN2010	YES	8:00	YES	18:45	
			18JAN2010	YES	7:45	YES	18:45	
			19JAN2010	YES	7:45	YES	19:00	
			20JAN2010	YES	6:45			
			20JAN2010			YES	18:45	
			21JAN2010	YES	7:30	YES	18:45	
			22JAN2010	YES	8:00	YES	18:45	
			23JAN2010	YES	7:30	YES	19:00	
			24JAN2010	YES	7:30	YES	18:45	
			25JAN2010	YES	8:00	YES	18:45	
			26JAN2010	YES	7:30	YES	18:45	
			27JAN2010	YES	8:00	YES	19:30	
			28JAN2010	YES	8:15	YES	18:45	
			29JAN2010	YES	7:45	YES	18:45	
			30JAN2010	YES	7:30	YES	18:45	
			31JAN2010	YES	7:45	YES	18:45	
			01FEB2010	YES	8:00	YES	18:45	
			02FEB2010	YES	7:45	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	03FEB2010	YES	7:45	YES	18:45	
			04FEB2010	YES	8:15	YES	18:45	
			05FEB2010	YES	7:45	YES	18:45	
			06FEB2010	YES	7:45	YES	18:45	
			07FEB2010	YES	8:00	YES	18:45	
			08FEB2010	YES	7:00	YES	18:45	
			09FEB2010	YES	7:45	YES	18:45	
			10FEB2010	YES	7:45	YES	18:45	
			11FEB2010	YES	7:30	YES	18:45	
			12FEB2010	YES	7:45	YES	18:45	
			13FEB2010	YES	8:00	YES	18:45	
			14FEB2010	YES	7:30	YES	18:45	
			15FEB2010	YES	8:00	YES	18:45	
			16FEB2010	YES	7:30	YES	18:45	
			17FEB2010	YES	8:00	YES	18:45	
			18FEB2010	YES	7:30	YES	18:45	
			19FEB2010	YES	7:45	YES	18:45	
			20FEB2010	YES	7:30	YES	18:45	
			21FEB2010	YES	7:45	YES	18:45	
			22FEB2010	YES	7:30	YES	18:45	
			23FEB2010	YES	8:00	YES	18:45	
			24FEB2010	YES	7:30	YES	18:45	
			25FEB2010	YES	7:45	YES	18:45	
			26FEB2010	YES	7:45	YES	18:45	
			27FEB2010	YES	7:45	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	28FEB2010	YES	8:00	YES	18:45	
			01MAR2010	YES	7:30	YES	18:45	
			02MAR2010	YES	7:45	YES	18:45	
			03MAR2010	YES	7:30	YES	18:45	
			04MAR2010	YES	7:30	YES	18:45	
			05MAR2010	YES	7:30	YES	18:45	
			06MAR2010	YES	7:45	YES	20:30	
			07MAR2010	YES	7:30	YES	18:45	
			08MAR2010	YES	7:30	YES	18:45	
			09MAR2010	YES	7:30	YES	18:45	
			10MAR2010	YES	7:30	YES	18:45	
			11MAR2010	YES	7:30	YES	18:45	
			12MAR2010	YES	7:30	YES	18:45	
			13MAR2010	YES	8:00	NO		Schlicht und einfach vergessen
			14MAR2010	YES	7:30	YES	18:45	
			15MAR2010	YES	7:30	YES	18:45	
			16MAR2010	YES	7:30	YES	18:45	
			17MAR2010	YES	7:30	YES	18:45	
			18MAR2010	YES	7:30	YES	18:45	
			19MAR2010	YES	7:15	YES	18:45	
			20MAR2010	YES	7:45	YES	18:45	
			21MAR2010	YES	7:30	YES	19:30	
			22MAR2010	YES	7:30	YES	18:45	
			23MAR2010	YES	7:15	YES	18:45	
			24MAR2010	YES	7:15	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	25MAR2010	YES	7:15	YES	18:45	
			26MAR2010	YES	7:15	YES	18:45	
			27MAR2010	YES	7:15	YES	18:45	
			28MAR2010	YES	7:45	YES	18:45	
			29MAR2010	YES	7:15	YES	18:45	
			30MAR2010	YES	7:15	YES	18:45	
			31MAR2010	YES	7:30	YES	18:45	
			01APR2010	YES	7:00	YES	18:45	
			02APR2010	YES	7:30	YES	19:30	
			03APR2010	YES	7:30	YES	18:45	
			04APR2010	YES	7:30	YES	18:45	
			05APR2010	YES	7:30	YES	18:45	
			06APR2010	YES	7:30	YES	18:45	
			07APR2010	YES	7:30	YES	18:45	
			08APR2010	YES	7:00	YES	18:45	
			09APR2010	YES	7:00	YES	18:45	
			10APR2010	YES	7:30	YES	18:45	
			11APR2010	YES	7:30	YES	18:45	
			12APR2010	YES	7:00	YES	18:45	
			13APR2010	YES	6:45			
			13APR2010	YES	7:00	YES	18:45	morgens noch eine Tablette v. Visit Nr. 4
			14APR2010	YES	7:00	YES	20:00	
			15APR2010	YES	7:00	YES	18:45	
			16APR2010	YES	7:00	YES	18:45	
			17APR2010	YES	7:00	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	18APR2010	YES	7:15	YES	18:45	
			19APR2010	YES	7:00	YES	18:45	
			20APR2010	YES	7:30	YES	18:45	
			21APR2010	YES	7:00	YES	18:45	
			22APR2010	YES	7:15	YES	18:45	
			23APR2010	YES	7:30	YES	18:45	
			24APR2010	YES	7:30	YES	18:45	
			25APR2010	YES	7:30	YES	20:00	
			26APR2010	YES	7:15	YES	18:45	
			27APR2010	YES	7:00	YES	18:45	
			28APR2010	YES	7:00	YES	18:45	
			29APR2010	YES	7:00	YES	18:45	
			30APR2010	YES	7:15	YES	18:45	
			01MAY2010	YES	7:15	YES	19:30	
			02MAY2010	YES	7:15	YES	19:30	
			03MAY2010	YES	7:30	YES	18:45	
			04MAY2010	YES	7:00	YES	18:45	
			05MAY2010	YES	7:30	YES	19:00	
			06MAY2010	YES	7:30	YES	20:30	
			07MAY2010	YES	7:30	YES	18:45	
			08MAY2010	YES	7:15	YES	18:45	
			09MAY2010	YES	7:15	YES	20:00	
			10MAY2010	YES	7:00	YES	18:45	
			11MAY2010	YES	7:00	YES	18:45	
			12MAY2010	YES	7:15	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	13MAY2010	YES	7:30	YES	18:45	
			14MAY2010		7:30	YES	18:45	
			15MAY2010	YES	7:00	YES	18:45	
			16MAY2010	YES	7:30	YES	18:45	
			17MAY2010	YES	7:15	YES	18:45	
			18MAY2010	YES	8:30	YES	18:45	Beim Hausarzt zur Blutabnahme, daher verspätete Einnahme
			19MAY2010	YES	7:00	YES	18:45	
			20MAY2010	YES	7:00	YES	18:45	
			21MAY2010	YES	7:00	YES	18:45	
			22MAY2010	YES	7:30	YES	18:45	
			23MAY2010	YES	7:30	YES	18:45	
			24MAY2010	YES	7:30	YES	18:45	
			25MAY2010	YES	7:00	YES	18:45	
			26MAY2010	YES	7:00	YES	18:45	
			27MAY2010	YES	7:30	YES	18:45	
			28MAY2010	YES	7:00	YES	18:45	
			29MAY2010	YES	7:30	YES	19:00	
			30MAY2010	YES	7:30	YES	18:45	
			31MAY2010	YES	7:00	YES	19:00	
			01JUN2010	YES	7:30	YES	18:45	
			02JUN2010	YES	7:00	YES	18:45	
			03JUN2010	YES	7:30	YES	18:45	
			04JUN2010	YES	7:00	YES	18:45	
			05JUN2010	YES	7:30	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	06JUN2010	YES	7:00	YES	19:00	
			07JUN2010	YES	7:00	YES	19:00	
			08JUN2010	YES	7:00	YES	19:00	
			09JUN2010	YES	8:00	YES	18:45	
			10JUN2010	YES	7:00	YES	19:00	
			11JUN2010	YES	7:00	YES	19:00	
			12JUN2010	YES	7:00	NO		vergessen
			13JUN2010	YES	8:00	YES	18:45	
			14JUN2010	YES	8:00	YES	18:45	
			15JUN2010	YES	7:00	YES	19:00	
			16JUN2010	YES	7:00	YES	19:00	
			17JUN2010	YES	7:00	YES	19:00	
			18JUN2010	YES	7:00	YES	19:00	
			19JUN2010	YES	7:00	YES	19:00	
			20JUN2010	YES	7:00	YES	20:00	
			21JUN2010	YES	8:00	YES	19:00	
			22JUN2010	YES	7:00	YES	19:00	
			23JUN2010	YES	7:00	YES	19:00	
			24JUN2010	YES	7:00	YES	19:00	
			25JUN2010	YES	7:00	YES	19:00	
			26JUN2010	YES	7:00	YES	19:00	
			27JUN2010	YES	7:00	YES	19:00	
			28JUN2010	YES	7:00	YES	19:00	
			29JUN2010	YES	7:00	YES	19:00	
			30JUN2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	01JUL2010	YES	7:00	YES	19:00	
			02JUL2010	YES	7:00	YES	19:00	
			03JUL2010	YES	7:00	YES	19:00	
			04JUL2010	YES	7:15	YES	19:00	
			05JUL2010	YES	7:00	YES	19:00	
			06JUL2010	YES	7:30	YES	19:00	
			07JUL2010	YES	7:00	YES	19:00	
			08JUL2010	YES	7:00	YES	19:00	
			09JUL2010	YES	7:00	YES	19:00	
			10JUL2010	YES	7:00	YES	19:30	
			11JUL2010	YES	7:00	YES	19:00	
			12JUL2010	YES	7:00	YES	19:15	
			13JUL2010	YES	7:00	YES	19:00	
			14JUL2010	YES	7:00	YES	19:00	
			15JUL2010	YES	7:00	YES	19:30	
			16JUL2010	YES	7:00	YES	19:00	
			17JUL2010	YES	7:00	YES	19:00	
			18JUL2010	YES	7:00	NO		vergessen
			19JUL2010	YES	7:00	YES	19:00	
			20JUL2010	YES	7:15	YES	19:30	
			21JUL2010	YES	7:00	YES	19:00	
			22JUL2010	YES	7:15	YES	19:00	
			23JUL2010	YES	7:15	YES	19:00	
			24JUL2010	YES	7:00	YES	19:00	
			25JUL2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	017	5	26JUL2010	YES	7:00	YES	19:00	Schulter Schmerzen (stark), Ibu-Hexal 400 mg, 2 Tab.
			27JUL2010	YES	7:00	YES	19:00	Spritze: Dexa-CT 8 mg/2 ml
			28JUL2010	YES	7:00	YES	19:00	Spritze: Dexa-CT 8 mg/2 ml
			29JUL2010	YES	7:00	YES	19:00	
			30JUL2010	YES	7:00	YES	19:00	Spritze: Dexa-CT 8 mg/2 ml
			31JUL2010	YES	7:00	YES	19:00	
			01AUG2010	YES	7:00	YES	19:00	
			02AUG2010	YES	7:30	YES	19:00	
			03AUG2010	YES	7:00			
	019	5	05JAN2009	YES	8:50	YES	20:10	
			06JAN2009	YES	7:10			
			21JUN2009	YES	6:30	YES	17:30	
			22JUN2009	YES	4:30	YES	17:00	
			09DEC2009	YES	9:30	YES	19:30	14:00: 1x Durchfall
			10DEC2009	YES	8:30	YES	19:45	
			11DEC2009	YES	9:00	YES	18:20	
			12DEC2009	YES	9:00	YES	18:30	
			13DEC2009	YES	9:30	YES	17:20	
			14DEC2009	YES	9:30	YES	18:30	
			15DEC2009	YES	9:30	YES	18:00	
			16DEC2009	YES	9:30	YES	18:00	
			17DEC2009	YES	8:45	YES	18:15	
			18DEC2009	YES	7:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	19DEC2009	YES	9:30	YES	22:30	
			20DEC2009	YES	9:00	YES	18:00	
			21DEC2009	YES	9:30	YES	18:30	
			22DEC2009	YES	9:00	YES	22:10	
			23DEC2009	YES	9:00	YES	21:10	
			24DEC2009	YES	8:45	YES	22:00	
			25DEC2009	YES	8:30	YES	21:00	
			26DEC2009	YES	9:00	YES	22:00	
			27DEC2009	YES	8:45	YES	19:30	
			28DEC2009	YES	8:30	YES	19:00	
			29DEC2009	YES	9:30	YES	22:00	
			30DEC2009	YES	9:00	YES	18:00	
			31DEC2009	YES	8:50	YES	19:00	
			01JAN2010	YES	9:30	YES	22:00	
			02JAN2010	YES	8:45	YES	20:30	
			03JAN2010	YES	9:00	YES	21:00	
			04JAN2010	YES	8:45	YES	18:15	
			07JAN2010	YES	9:00	YES	18:15	
			08JAN2010	YES	8:00	YES	19:00	
			09JAN2010	YES	9:00	YES	21:45	
			10JAN2010	YES	8:00	YES	17:30	
			12JAN2010	YES	7:00	YES	20:45	
			13JAN2010	YES	7:00	YES	18:00	
			14JAN2010	YES	6:45	YES	18:15	
			15JAN2010	YES	7:30	YES	21:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	16JAN2010	YES	9:00	YES	20:30	
			17JAN2010	YES	8:00	YES	17:00	
			18JAN2010	YES	7:30	YES	18:30	
			19JAN2010	YES	6:45	YES	17:30	
			20JAN2010	YES	6:30	YES	17:30	
			21JAN2010	YES	7:00	YES	18:00	
			22JAN2010	YES	7:00	YES	17:15	
			23JAN2010	YES	9:00	YES	21:45	
			24JAN2010	YES	8:00	YES	20:30	
			25JAN2010	YES	6:45	YES	17:30	
			26JAN2010	YES	7:00	YES	17:30	
			27JAN2010	YES	6:30	YES	18:00	
			28JAN2010	YES	7:30	YES	20:30	
			29JAN2010	YES	6:45	YES	18:00	
			30JAN2010	YES	8:00	YES	17:30	
			31JAN2010	YES	9:00	YES	20:00	
			01FEB2010	YES	7:30	YES	18:00	
			02FEB2010	YES	7:15	YES	17:45	
			03FEB2010	YES	7:10	YES	17:30	
			04FEB2010	YES	7:00	YES	17:20	
			05FEB2010	YES	6:45	YES	5:45	
			06FEB2010	YES	8:00	YES	22:00	
			07FEB2010	YES	11:00	YES	18:00	
			08FEB2010	YES	6:30	YES	21:00	
			09FEB2010	YES	7:00	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	10FEB2010	YES	6:30	YES	18:00	
			11FEB2010	YES	7:45	YES	18:00	
			12FEB2010	YES	6:45	YES	21:00	
			13FEB2010	YES	8:00	YES	19:30	
			14FEB2010	YES	8:30	YES	18:30	
			15FEB2010	YES	7:30	YES	17:15	
			16FEB2010	YES	7:15	YES	18:30	
			17FEB2010	YES	6:25	YES	19:00	
			18FEB2010	YES	6:45	YES	18:30	
			19FEB2010	YES	7:00	YES	17:30	
			20FEB2010	YES	9:00	YES	19:30	
			21FEB2010	YES	8:00	YES	19:30	
			22FEB2010	YES	7:20	YES	21:00	
			23FEB2010	YES	7:00	YES	17:30	
			24FEB2010	YES	7:45	YES	18:00	
			25FEB2010	YES	6:45	YES	19:45	
			26FEB2010	YES	7:15	YES	18:15	
			27FEB2010	YES	7:30	YES	17:40	
			28FEB2010	YES	8:00	YES	18:15	
			01MAR2010	YES	6:50	YES	17:30	
			02MAR2010	YES	9:00	YES	18:30	
			03MAR2010	YES	6:30			
			03MAR2010	YES		YES	21:00	
			04MAR2010	YES	6:30	YES	21:00	
			05MAR2010	YES	7:00	YES	17:40	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	06MAR2010	YES	8:00	YES	18:30	
			07MAR2010	YES	8:00	YES	17:00	
			08MAR2010	YES	6:15	YES	21:00	
			09MAR2010	YES	6:45	YES	17:30	
			10MAR2010	YES	8:30	YES	17:00	
			11MAR2010	YES	6:45	YES	18:30	
			12MAR2010	YES	7:00	YES	18:30	
			13MAR2010	YES	9:00	YES	18:30	
			14MAR2010	YES	8:00	YES	18:15	
			15MAR2010	YES	7:00	YES	19:30	
			16MAR2010	YES	7:30	YES	19:00	
			17MAR2010	YES	7:00	YES	19:15	
			18MAR2010	YES	7:00	YES	21:00	
			19MAR2010	YES	7:00	YES	18:00	
			20MAR2010	YES	6:15	YES	18:00	
			21MAR2010	YES	9:00	YES	18:00	
			22MAR2010	YES	6:00	YES	18:30	
			23MAR2010	YES	8:30	YES	19:15	
			24MAR2010	YES	8:00	YES	20:15	
			25MAR2010	YES	9:00	YES	19:00	
			26MAR2010	YES	6:30	YES	18:00	
			27MAR2010	YES	7:00	YES	18:30	
			28MAR2010	YES	7:30	YES	20:30	
			29MAR2010	YES	8:00	YES	18:00	
			30MAR2010	YES	8:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	31MAR2010	YES	7:30	YES	19:00	
			01APR2010	YES	6:30	YES	19:00	
			02APR2010	YES	8:00	YES	18:00	
			03APR2010	YES	8:30	YES	20:30	
			04APR2010	YES	7:30	YES	19:20	
			05APR2010	YES	7:00	YES	19:00	
			06APR2010	YES	7:30	YES	18:00	
			07APR2010	YES	6:00	YES	18:45	
			08APR2010	YES	6:30	YES	18:30	
			09APR2010	YES	7:00	YES	19:45	
			10APR2010	YES	5:30	YES	19:45	
			11APR2010	YES	8:30	YES	17:30	
			12APR2010	YES	8:00	YES	18:00	
			13APR2010	YES	6:30	YES	19:00	
			14APR2010	YES	9:00	YES	18:15	
			15APR2010	YES	8:00	YES	18:00	
			16APR2010	YES	8:00	YES	19:00	
			17APR2010	YES	8:00	YES	18:45	
			18APR2010	YES	7:30	YES	19:15	
			19APR2010	YES	8:15	YES	18:00	
			20APR2010	YES	7:30	YES	18:30	
			21APR2010	YES	7:00	YES	20:00	
			22APR2010	YES	8:00	YES	18:30	
			23APR2010	YES	6:45	YES	22:30	
			24APR2010	YES	7:00	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	25APR2010	YES	7:30	YES	21:00	
			26APR2010	YES	7:30	YES	19:00	
			27APR2010	YES	6:30	YES	22:00	
			28APR2010	YES	7:15	YES	20:30	
			29APR2010	YES	7:30	YES	19:00	
			30APR2010	YES	7:45	YES	22:00	
			01MAY2010	YES	6:00	YES	21:30	
			02MAY2010	YES	7:15	YES	18:36	
			03MAY2010	YES	8:00	YES	20:00	
			04MAY2010	YES	5:45	YES	19:15	
			05MAY2010	YES	8:00	YES	20:45	
			06MAY2010	YES	9:30	YES	19:30	
			07MAY2010	YES	5:45	YES	18:30	
			08MAY2010	YES	5:45	YES	18:00	
			09MAY2010	YES	6:20	YES	18:45	
			10MAY2010	YES	7:00	YES	18:00	
			11MAY2010	YES	7:30	YES	18:00	
			12MAY2010	YES	6:30	YES	19:20	
			13MAY2010	YES	7:00	YES	18:15	
			14MAY2010	YES	7:15	YES	18:30	
			15MAY2010	YES	8:30	YES	19:00	
			16MAY2010	YES	8:00	YES	19:00	
			17MAY2010	YES	6:00	YES	18:30	
			18MAY2010	YES	7:00	YES	19:15	
			19MAY2010	YES	6:00	YES	19:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	20MAY2010	YES	8:00	YES	18:30	
			21MAY2010	YES	7:15	YES	20:00	
			22MAY2010	YES	6:30	YES	18:00	
			23MAY2010	YES	5:00	YES	22:30	
			24MAY2010	YES	6:00	YES	19:30	
			25MAY2010	YES	7:00			
			25MAY2010			YES	18:00	
			26MAY2010	YES	8:00	YES	20:30	
			27MAY2010	YES	9:00	YES	20:30	
			28MAY2010	YES	9:00	YES	19:00	
			29MAY2010	YES	8:00	YES	21:30	
			30MAY2010	YES	9:30	YES	18:00	
			31MAY2010	YES	8:00	YES	19:00	
			01JUN2010	YES	7:00	YES	18:30	
			02JUN2010	YES	6:30	YES	17:15	
			03JUN2010	YES	6:00	YES	18:00	
			04JUN2010	YES	6:20	YES	21:00	
			05JUN2010	YES	8:00	YES	22:00	
			06JUN2010	YES	6:30	YES	19:20	
			07JUN2010	YES	8:15	YES	20:15	
			08JUN2010	YES	6:30	YES	21:15	
			09JUN2010	YES	6:40	YES	22:00	
			10JUN2010	YES	5:00	YES	17:00	
			11JUN2010	YES	4:45	YES	18:00	
			12JUN2010	YES	7:15	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	13JUN2010	YES	7:30	YES	19:30	
			14JUN2010	YES	6:30	YES	18:45	
			15JUN2010	YES	7:30	YES	21:00	
			16JUN2010	YES	6:30	YES	21:00	
			17JUN2010	YES	6:30	YES	18:30	
			18JUN2010	YES	6:30	YES	17:30	
			19JUN2010	YES	6:15	YES	21:00	
			20JUN2010	YES	6:00	YES	18:30	
			23JUN2010	YES	6:30	YES	19:00	
			24JUN2010	YES	6:30	YES	17:15	
			25JUN2010	YES	6:15	YES	18:45	
			26JUN2010	YES	8:00	YES	21:00	
			27JUN2010	YES	8:00	YES	19:15	
			28JUN2010	YES	6:45	YES	18:30	
			29JUN2010	YES	7:10			
			30JUN2010	YES	6:15	YES	19:00	
			01JUL2010	YES	6:30	YES	19:00	
			02JUL2010	YES	6:30	YES	18:30	
			03JUL2010	YES	8:00	YES	17:30	
			04JUL2010		8:30	YES	18:45	
			05JUL2010	YES	6:30	YES	19:45	
			06JUL2010	YES	6:30	YES	19:30	
			07JUL2010	YES	6:00	YES	20:00	
			08JUL2010	YES	6:00	YES	19:00	
			09JUL2010	YES	6:15			

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	10JUL2010	YES	6:30			
			11JUL2010	YES	8:45		18:45	
			12JUL2010	YES	7:00	YES	18:30	
			13JUL2010	YES	9:30	YES	21:00	
			14JUL2010	YES	6:30	YES	20:40	
			15JUL2010	YES	6:50	YES	19:50	
			16JUL2010	YES	6:30	YES	21:00	
			17JUL2010	YES	6:45	YES	20:00	
			18JUL2010	YES	10:00	YES	19:30	
			19JUL2010	YES	9:15	YES	17:00	
			20JUL2010	YES	8:00	YES	22:00	
			21JUL2010	YES	7:30	YES	18:00	
			22JUL2010	YES	7:30	YES	22:00	
			23JUL2010	YES	7:30	YES	19:15	
			24JUL2010	YES	10:00	YES	20:15	
			25JUL2010	YES	7:00	YES	21:15	
			26JUL2010	YES	6:30	YES	21:15	
			27JUL2010	YES	7:00	YES	20:00	
			28JUL2010	YES	8:00	YES	19:45	
			29JUL2010	YES	7:45	YES	20:00	
			30JUL2010	YES	7:00	YES	21:10	
			31JUL2010	YES	8:30	YES	19:00	
			01AUG2010	YES	7:30	YES	21:00	
			02AUG2010	YES	8:30	YES	20:00	
			03AUG2010	YES	9:00	YES	20:15	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	04AUG2010	YES	7:45		19:00	
			05AUG2010	YES	8:00	YES	18:30	
			06AUG2010	YES	8:00			
			07AUG2010	YES	9:00	YES	21:00	
			08AUG2010	YES	9:30	YES	19:00	
			09AUG2010	YES	7:45	YES	21:00	
			10AUG2010	YES	6:30			
			13AUG2010	YES	9:30	YES	18:45	
			15AUG2010	YES	9:30	YES	20:15	
			16AUG2010	YES	10:00	YES	20:00	
			17AUG2010	YES	8:00	YES	19:30	
			18AUG2010	YES	8:00	YES	18:45	
			19AUG2010	YES	7:00	YES	19:15	
			20AUG2010	YES	7:30	YES	21:00	
			21AUG2010	YES	8:45	YES	18:30	
			22AUG2010	YES	9:00	YES	20:30	
			23AUG2010	YES	8:00	YES	20:00	
			24AUG2010	YES	7:30			
			24AUG2010			YES	21:20	
			25AUG2010			YES	19:20	
			26AUG2010	YES	9:30	YES	19:00	
			27AUG2010	YES	8:45	YES	20:45	
			28AUG2010	YES	8:30	YES	17:00	
			29AUG2010	YES	7:00	YES	18:00	
			30AUG2010	YES	7:00	YES	18:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	31AUG2010	YES	7:00	YES	18:00	
			01SEP2010	YES	7:00	YES	18:00	
			02SEP2010	YES	7:00	YES	18:00	
			03SEP2010	YES	7:00	YES	18:00	
			04SEP2010	YES	7:00	YES	18:00	
			05SEP2010	YES	7:00	YES	18:00	
			06SEP2010	YES	7:00	YES	18:00	
			07SEP2010	YES	7:00	YES	18:00	
			08SEP2010	YES	7:00	YES	18:00	
			09SEP2010	YES	7:00	YES	18:00	
			10SEP2010	YES	7:00	YES	18:00	
			11SEP2010	YES	7:00	YES	18:00	
			12SEP2010	YES	7:00	YES	20:45	
			13SEP2010	YES	8:30	YES	20:00	
			14SEP2010	YES	9:45	YES	19:00	
			15SEP2010	YES	8:15	YES	19:30	
			16SEP2010	YES	8:15	YES	20:00	
			17SEP2010	YES	9:00	YES	20:00	
			18SEP2010	YES	11:00	YES	19:30	
			19SEP2010	YES	8:30	YES	19:30	
			20SEP2010	YES	8:00	YES	18:00	
			21SEP2010	YES	8:00	YES	19:15	
			22SEP2010	YES	7:15	YES	19:45	
			23SEP2010	YES	7:30	YES	20:00	
			24SEP2010	YES	7:15	YES	20:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	25SEP2010	YES	8:00	YES	19:00	
			26SEP2010	YES	9:00	YES	21:00	
			27SEP2010	YES	8:30	YES	19:00	
			28SEP2010	YES	8:00	YES	18:00	
			29SEP2010	YES	7:15	YES	18:45	
			30SEP2010	YES	7:20	YES	19:00	
			01OCT2010	YES	7:20	YES	18:30	
			02OCT2010	YES	7:25	YES	19:15	
			03OCT2010	YES	7:15	YES	19:45	
			04OCT2010	YES	7:20	YES	20:00	
			05OCT2010	YES	7:30	YES	20:10	
			06OCT2010	YES	7:45	YES	19:55	
			07OCT2010	YES	8:00	YES	19:45	
			08OCT2010	YES	7:45	YES	19:15	
			09OCT2010	YES	8:00	YES	20:15	
			10OCT2010	YES	8:15	YES	19:30	
			11OCT2010	YES	8:30	YES	18:20	
			11OCT2010	YES	7:00	YES	20:00	
			12OCT2010	YES	7:00	YES	19:45	
			13OCT2010	YES	9:45	YES	19:00	
			14OCT2010	YES	7:00	YES		
			15OCT2010	YES	7:45	YES	21:00	
			16OCT2010	YES	8:00	NO		Darmausgang "brennt"
			17OCT2010	YES	10:00	YES	19:30	
			18OCT2010	YES	7:45	YES	20:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	19OCT2010	YES	7:30	YES	19:00	
			20OCT2010	YES	7:30	YES	18:45	
			21OCT2010	YES	8:00	YES	21:00	
			22OCT2010	YES	7:30	YES	21:00	
			23OCT2010	YES	8:00	YES	18:15	
			24OCT2010	YES	8:00	YES	20:30	
			25OCT2010	YES	7:30	YES	21:30	
			26OCT2010	YES	8:40	YES	21:00	
			27OCT2010	YES	8:00	YES	21:00	
			28OCT2010	YES	8:00	YES	19:00	
			29OCT2010	YES	9:00	YES	18:00	
			30OCT2010	YES	8:00	YES	18:30	
			01NOV2010	YES	8:00	YES	18:00	
			02NOV2010	YES	9:00	YES	21:45	
			03NOV2010	YES	8:00	YES	20:00	
			04NOV2010	YES	7:30	YES	18:00	
			05NOV2010	YES	8:30	YES	20:00	
			06NOV2010	YES	9:00	YES	19:00	
			07NOV2010	YES	7:30	YES	18:00	
			08NOV2010	YES	8:00	YES	17:45	
			09NOV2010	YES	8:00	YES	19:00	
			10NOV2010	YES	10:00	YES	20:00	
			11NOV2010	YES	8:30	YES	18:00	
			12NOV2010	YES	8:00	YES	21:00	
			13NOV2010	YES	9:00	YES	19:30	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	019	5	14NOV2010	YES	9:30	YES	17:00	
			15NOV2010	YES	9:00	YES	21:45	
			16NOV2010	YES	9:10	YES	19:00	
			17NOV2010	YES	8:30	YES	19:30	
			18NOV2010	YES	8:00	YES	19:30	
			19NOV2010	YES	8:00	YES	21:10	
			20NOV2010	YES	8:00	YES	19:30	
			21NOV2010	YES	9:00	YES	19:00	
			22NOV2010	YES	8:30	YES	17:00	
			23NOV2010	YES	8:00	YES	19:00	
			24NOV2010	YES	8:00	YES	19:45	
			25NOV2010	YES	8:00	YES	19:00	
			26NOV2010	YES	9:00	YES	20:30	
			27NOV2010	YES	9:00	YES	20:00	
			28NOV2010	YES	9:30	YES	22:30	
			29NOV2010	YES	10:00	YES	19:00	
			30NOV2010	YES	9:00	YES	19:00	
			01DEC2010	YES	9:00	YES	19:30	
			02DEC2010	YES	7:00	YES	17:30	
			03DEC2010	YES	7:30	YES	18:00	
			04DEC2010	YES	9:15	YES	20:00	
			05DEC2010	YES	10:00	YES	18:00	
			06DEC2010	YES	9:30	YES	20:00	
			07DEC2010	YES	7:00			

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	20JUL2010	YES	12:00	YES	18:25	leichter Druckschmerz in der Nähe des Steißbeins. Am Abend 21.30 Uhr nahm der Schmerz zu.
			21JUL2010	YES	6:45	YES	12:15	am Morgen keinen Druckschmerz mehr. Am Nachmittag trockener Mund.
			22JUL2010	YES	7:00	YES	18:40	leichter trockener Mund beim Wandern.
			23JUL2010	YES	7:30	YES	18:05	leichtes Unwohlsein nach Einnahme der Tablette. Dann beim Frühstück alles o.k.
			24JUL2010	YES	7:00		19:12	Anschließend gefröstelt. Um 9:00 am 24.7. gefröstelt, etwas trockener Mund.
			25JUL2010	YES	5:20	YES	18:25	am Abend mit Epi Pevaryl Creme Füße eingecremt gegen Fußpilz. (Urlaub in den Dolomiten v. 25. - 31.7.) mit tägl. Wanderungen.
			26JUL2010	YES	6:30	YES	18:20	am Abend Epi Pevaryl Creme für Füße gegen Fußpilz. Essen am Abend in Pension schmeckte nicht. Apetitt war nicht so groß.
			27JUL2010	YES	6:30	YES	18:25	am Abend nach der Wanderung keinen großen Apetitt.
			28JUL2010	YES	6:35	YES	18:15	am Nachmittag leichtes Stechen im li. Ohr + linke Schläfe. Mit Epi Pervaryl Füße eingecremt
			29JUL2010	YES	6:30		18:25	li. Schläfe leichtes Stechen leicht verwirrt. Fragte, ob wir in Deutschland sind, obwohl wir in den Dolomiten waren.
			30JUL2010	YES	6:30	YES	18:15	Am Abend Epi Pervaryl Creme gegen Fußpilz eingecremt. Keine Verwirrtheit mehr.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	31JUL2010	YES	6:35	YES	20:05	Dolomitenurlaub zu Ende. Am Vormittag noch Wanderung von ca. 3 1/2 Std. Dann um 16:00 Uhr Heimreise mit Bus.
			01AUG2010	YES	7:20	YES	19:00	Geschmacksnerven veränderten sich.
			02AUG2010	YES	6:30	YES	18:45	immer etwas müde. Apetitt wieder normal auch das Geschmacksempfinden.
			03AUG2010	YES	7:30		19:45	Füße eingecremt mit Epi Pervaryl am Abend.
			04AUG2010	YES	7:30	YES	17:35	Füße eingecremt mit Epi Pervaryl am Abend.
			05AUG2010	YES	8:00	YES	18:25	Füße eingecremt mit Epi Pervaryl am Abend.
			06AUG2010	YES	7:30	YES	18:55	Füße eingecremt mit Epi Pervaryl am Abend. 3 Globuli Alumina D12
			07AUG2010	YES	7:55	YES	19:00	5 Globuli Alumina D12. Trockener Mund. Epi Pervaryl Creme für die Füße.
			08AUG2010	YES	7:25	YES	17:25	heute Morgen leichte Übelkeit und innerliches leichtes schwäche Gefühl. 4 Globuli Alumina D12.
			09AUG2010	YES	7:30	YES	18:05	Am Abend wieder besser. Epi Pervaryl Creme f. d. Füße gegen Fußpilz.
			10AUG2010	YES	8:15	YES	18:30	innerliche Unruhe am Morgen. Im Laufe des Tages wieder alles normal.
			11AUG2010	YES	8:05	YES	18:12	Epi Pervaryl für die Füße gegen Fußpilz.
			12AUG2010	YES	7:16			leichte Bauchschmerzen von 8.15 - 8.20 Uhr
			12AUG2010			YES	17:50	immer müde
			13AUG2010	YES	6:45	YES	17:15	leichtes Unwohlsein von 09:45 Uhr - 09:55 Uhr müde leichtes Frösteln.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	15AUG2010	YES	6:55	NO		Wir gingen am Abend zum Essen und haben deshalb die Tablette vergessen.
			16AUG2010	YES	7:30	YES	18:05	
			17AUG2010	YES	7:45	YES	18:05	Epi Pervaryl Creme gegen Fußpilz am rechten Fuß eingecremt
			18AUG2010	YES	7:40	YES	18:30	Epi Pervaryl Creme gegen Fußpilz am rechten Fuß eingecremt
			19AUG2010	YES	6:00	YES	19:40	Um 10:00 Uhr Aufstieg zum Pendling, es war keine körperliche Schwäche, da Tablette bereits um 6:00 Uhr eingenommen wurde.
			20AUG2010	YES	7:15	YES	18:00	
			21AUG2010	YES	6:35	YES	18:25	
			22AUG2010	YES	6:45	YES	19:10	
			23AUG2010	YES	7:10	YES	18:15	
			24AUG2010	YES	7:30	YES	18:20	am Nachmittag 17:00 Uhr leichter Durchfall (3 Mal) bis 17:30 Uhr
			25AUG2010	YES	7:35		18:40	
			26AUG2010	YES	7:00	YES	18:30	
			27AUG2010	YES	6:55	YES	18:55	
			28AUG2010	YES	6:50	YES	22:25	
			29AUG2010	YES	8:00	YES	18:15	
			30AUG2010	YES	6:35	YES	18:05	1 Aspirin 100 mg
			31AUG2010	YES	7:05	YES	18:05	
			01SEP2010	YES	6:00	YES	17:45	
			02SEP2010	YES	6:00	YES	19:20	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	03SEP2010	YES	7:30	YES	18:45	1 Aspirin 100 mg
			04SEP2010	YES	7:35	YES	18:00	Ab Mittag ca. 12:00 Uhr leichtes Frieren + Unwohl sein bis 20:00 Uhr
			05SEP2010	YES	8:25	YES	18:40	
			06SEP2010	YES	7:15	YES	18:25	10 Minuten leichtes Unwohl sein nach Einnahme der Tablette um 7:15 Uhr
			07SEP2010	YES	7:30	YES	18:45	10:00-11:30 müde, etwas gefroren + beim Schlafen Muskel zucken
			08SEP2010	YES	8:05	YES	18:20	3 Globuli Alumina hohe Potenz genommen. Wirkt sehr gut. Geht ihm wesentlich besser.
			09SEP2010	YES	6:50	YES	17:50	Morgens nach Einnahme von Tablette zitterig, wollen wandern gehen, vielleicht deswegen?
			10SEP2010	YES	7:45	YES	22:50	Epi Pervaryl Creme am Abend Füße eingecremt. Ab heute wirkt Globuli.
			11SEP2010	YES	7:50	YES	18:00	
			12SEP2010	YES	7:35	YES	19:00	keine Schwäche beim Üben. Es ging alles ganz gut.
			13SEP2010	YES	8:00	YES	18:40	müde leichtes Schwächegefühl von ca. 13:00-16:00 Uhr nach Schlaf war es wieder gut.
			14SEP2010	YES	7:20	YES	18:20	
			15SEP2010	YES	7:35	YES	20:00	
			16SEP2010	YES	6:05	YES	19:10	
			17SEP2010	YES	7:15	YES	19:50	Zur Zeit ergotherapeutische Übungen. Heute bei Übung wieder Schwächegefühl, etwas zitterig von ca. 10:00-13:00
			18SEP2010	YES	7:00	YES	18:15	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	19SEP2010	YES	7:00	YES	18:10	
			20SEP2010	YES	7:10	YES	18:10	
			21SEP2010	YES	7:30	YES	19:10	am Abend mit Epipervaryl-Creme Füße eingecremt.
			22SEP2010	YES	6:50	YES	21:00	
			23SEP2010	YES	6:00	YES	19:50	
			24SEP2010	YES	7:00	YES	18:00	
			25SEP2010	YES	7:20	YES	16:45	
			26SEP2010	YES	7:45	YES	18:35	
			27SEP2010	YES	7:55	YES	17:30	
			28SEP2010	YES	7:45	YES	18:40	
			29SEP2010	YES	7:40	YES	20:05	
			30SEP2010	YES	7:30	YES	18:30	
			01OCT2010	YES	8:15	YES	19:10	
			02OCT2010	YES	7:10	YES	17:30	
			03OCT2010	YES	7:10	YES	18:35	
			04OCT2010	YES	7:45	YES	18:20	
			05OCT2010	YES	7:30	YES	19:30	
			06OCT2010	YES	7:20	YES	19:30	
			07OCT2010	YES	7:10	YES	17:30	Vom 7.10.2010 bis 10.10.2010 mit Wohnmobil in die Jachenau.
			08OCT2010	YES	7:45	YES	17:05	beim Wandern auf das Hirschhörndlköpferl keine Probleme
			09OCT2010	YES	7:35	YES	19:35	beim Wandern an der Isar 3x zittrig und leichtes Unwohlsein

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	10OCT2010	YES	6:40	YES	19:30	beim Wandern auf den Rabenkopf nur beim Abstieg kurz ein leichtes Unwohlsein (5 Minuten).
			11OCT2010	YES	6:50	YES	18:35	
			12OCT2010	YES	7:10	YES	19:00	
			13OCT2010	YES		YES	19:50	tagsüber immer zwischendurch müde
			13OCT2010	YES	6:30			
			14OCT2010	YES	6:30	YES	19:00	tagsüber immer zwischendurch müde
			15OCT2010	YES	7:00	YES	18:10	tagsüber immer zwischendurch müde
			16OCT2010	YES	6:50	YES	18:30	tagsüber immer zwischendurch müde
			17OCT2010	YES	7:30	YES	19:00	tagsüber immer zwischendurch müde
			18OCT2010	YES	6:45	YES	17:20	tagsüber immer zwischendurch müde
			19OCT2010	YES	6:55	YES	18:25	tagsüber immer zwischendurch müde
			20OCT2010	YES	7:00	YES	18:30	Belastungs EKG war in Ordnung
			21OCT2010	YES	6:50	YES	18:10	bisher keine leichten Schwächezustände mehr.
			22OCT2010	YES	7:30	YES	19:25	tagsüber immer mal müde
			23OCT2010	YES	7:30	YES	15:20	tagsüber immer mal müde
			24OCT2010	YES	7:10	YES	18:40	tagsüber immer mal müde
			25OCT2010	YES	6:30	YES	19:03	tagsüber immer mal müde
			26OCT2010	YES	6:40	YES	18:20	tagsüber immer mal müde
			27OCT2010	YES	8:04	YES	18:00	tagsüber immer mal müde
			28OCT2010	YES	6:50	YES	18:02	tagsüber immer mal müde
			29OCT2010	YES	7:05	YES	18:00	tagsüber immer mal müde
			30OCT2010	YES	7:25	YES	17:30	Beim Üben heute ca. 5 Min. leichte Übelkeit.
			31OCT2010	YES	7:35	YES	17:05	tagsüber immer mal müde
			01NOV2010	YES	7:50	YES	18:00	tagsüber immer mal müde

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	02NOV2010	YES	6:15	YES	18:30	Um 08:00 Uhr Walking ca. 3/4 Std. danach zu Hause leichtes Schwächegefühl ca. 5 Minuten.
			03NOV2010	YES	6:20	YES	18:35	Epi-Pevaryl-Creme gegen Fußpilz
			04NOV2010	YES	6:30	YES	18:35	Epi-Pevaryl-Creme gegen Fußpilz
			05NOV2010	YES	5:00	YES	19:10	vom 05.11.-07.11. Busreise nach Dresden, bei Stadtbesichtigung in Dresden beim Treppen hinabgehen gestürzt.
			06NOV2010	YES	6:40	YES	16:45	Keine Blessuren/alles ok. Beim Alleingang ängstlich+besorgt am 1.Tag in Dresden, daß wir den Treffpunkt unseres Busses nicht rechtzeitig finden würden!
			07NOV2010	YES	7:20	YES	20:55	
			08NOV2010	YES	6:11	YES	18:05	
			09NOV2010	YES	6:30	YES	17:50	5 Globuli Alumina D12. Hohe Potenz, tagsüber immer mal müde
			10NOV2010	YES	6:11	YES	21:25	5 Globuli Alumina D12, Abendessen um 19:30 Uhr, Tablette vergessen vorher zum Einnehmen.
			11NOV2010	YES	6:40	YES	18:53	5 Globuli Alumina D12
			12NOV2010	YES	6:35	YES	19:07	tagsüber immer mal müde
			13NOV2010	YES	7:05	YES	18:15	tagsüber immer mal müde
			14NOV2010	YES	7:00	YES	18:05	tagsüber immer mal müde
			15NOV2010	YES	6:35	YES	18:15	tagsüber immer mal müde
			16NOV2010	YES	6:25	YES	18:05	Epi Pevaryl Creme gegen Fußpilz am Abend eingecremt.
			17NOV2010	YES	6:40	YES	18:00	Epi Pevaryl gegen Fußpilz am Abend eingecremt.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	18NOV2010	YES	6:30	YES	18:15	Epi Pevaryl gegen Fußpilz am Abend eingecremt.
			19NOV2010	YES	6:55	YES	18:25	Epi Pevaryl gegen Fußpilz am Abend eingecremt.
			20NOV2010	YES	6:45	YES	18:50	Epi Pevaryl gegen Fußpilz am Abend eingecremt.
			21NOV2010	YES	6:35	YES	18:40	Epi Pevaryl gegen Fußpilz am Abend eingecremt.
			22NOV2010	YES	6:40	YES	16:30	Epi Pevaryl gegen Fußpilz am Abend eingecremt.
			23NOV2010	YES	9:05	YES	18:22	Epi Pevaryl gegen Fußpilz am Abend eingecremt.
			24NOV2010	YES	7:00	YES	21:00	Epi Pevaryl gegen Fußpilz am Abend eingecremt.
			25NOV2010	YES	8:30	YES	18:20	Epi Pevaryl gegen Fußpilz am Morgen eingecremt.
			26NOV2010	YES	7:45	YES	17:53	Epi Pevaryl gegen Fußpilz am Morgen eingecremt.
			27NOV2010	YES	7:45	YES	18:05	Epi Pevaryl Creme gegen Fußpilz
			28NOV2010	YES	7:00	YES	17:55	Epi Pevaryl Creme gegen Fußpilz
			29NOV2010	YES	7:30	YES	19:30	Epi Pevaryl Creme gegen Fußpilz
			30NOV2010	YES	7:40	YES	18:20	Epi Pevaryl Creme gegen Fußpilz
			01DEC2010	YES	7:00	YES	18:25	Epi Pevaryl Creme gegen Fußpilz
			02DEC2010	YES	6:15	YES	19:00	Epi Pevaryl Creme gegen Fußpilz
			03DEC2010	YES	7:00	YES	17:45	Epi Pevaryl Creme gegen Fußpilz
			04DEC2010	YES	6:35	YES	18:00	Epi Pevaryl Creme gegen Fußpilz
			05DEC2010	YES	6:50	YES	18:30	Epi Pevaryl Creme gegen Fußpilz
			06DEC2010	YES	6:35	YES	18:25	Epi Pevaryl-Creme am Mittag gegen Fußpilz.
			07DEC2010	YES	6:25	YES	18:25	Epi Pevaryl-Creme am Mittag gegen Fußpilz.
			08DEC2010	YES	7:25	YES	20:00	Epi Pevaryl-Creme am Mittag gegen Fußpilz.
			09DEC2010	YES	8:30	YES	18:10	Sinupret forte 3x2 Tabletten tägl. gegen Nebenhöhlenentzündung.
			10DEC2010	YES	6:45	YES	19:30	2x3 Sinupret forte
			11DEC2010	YES	6:50	YES	18:45	Epi Pevaryl Creme gegen Fußpilz

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	12DEC2010	YES	7:20	YES	18:00	Epi Pevaryl Creme gegen Fußpilz
			13DEC2010	YES	7:30	YES	18:15	Epi Pevaryl Creme abends
			14DEC2010	YES	6:15	YES	18:10	Epi Pevaryl Creme morgens
			15DEC2010	YES	7:40	YES	18:50	Epi Pevaryl Creme re. Fuß mittags eingecremt gegen Fußpilz
			16DEC2010	YES	8:15	YES	17:35	Epi Pevaryl Creme re. Fuß mittags eingecremt gegen Fußpilz
			17DEC2010	YES	7:35	YES	18:05	Epi Pevaryl Creme re. Fuß mittags eingecremt gegen Fußpilz
			18DEC2010	YES	7:30	YES	18:10	Epi Pevaryl Creme re. Fuß mittags eingecremt gegen Fußpilz
			19DEC2010	YES	7:00	YES	19:35	Epi Pevaryl Creme re. Fuß mittags eingecremt gegen Fußpilz
			20DEC2010	YES	7:00	YES	18:25	nach vorheriger Schreibübung (1 Wort) von 08:00-08:10 Uhr innerliches Frieren, leichte Schwäche+Übelkeit, konnte nichts essen
			21DEC2010	YES	7:35	YES	17:50	Epi Pevaryl Creme gegen Fußpilz
			22DEC2010	YES	7:05	YES	19:10	3 Globuli Alumina hohe Potenz, Epi Pevaryl Creme
			23DEC2010	YES	6:45	YES	18:10	Epi Pevaryl Creme
			24DEC2010	YES	7:00	YES	18:25	tagsüber immer mal müde
			25DEC2010	YES	8:15	YES	18:55	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz
			26DEC2010	YES	7:20	YES	18:20	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	27DEC2010	YES	8:20	YES	23:40	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz
			28DEC2010	YES	8:40		19:30	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz
			29DEC2010	YES	7:35	YES	18:25	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz
			30DEC2010	YES	8:00	YES	18:00	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz
			31DEC2010	YES	6:40	YES	18:10	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz
			01JAN2011	YES	8:05	YES	18:00	tagsüber immer mal müde, Epi Pevaryl Creme gegen Fußpilz
			02JAN2011	YES	7:30	YES	19:20	tagsüber immer mal müde, tägl. Epi Pevaryl Creme gegen Fußpilz
			03JAN2011	YES	7:40	YES	18:25	am Morgen Schwindel vom 06:30-07:00 Uhr, von 07:40-08:00 dann vorbei.
			04JAN2011	YES	7:05	YES	19:30	Epi Pevaryl Creme
			05JAN2011	YES	7:55	YES	18:35	friert immer wieder, zur Vorsorgeuntersuchung beim Urologen
			06JAN2011	YES	9:30	YES	18:20	Epi Pevaryl, friert immer wieder (3 Globuli Aluminium, 1 Pflaster Kentera) vom Urologen verschrieben gegen häufiges Wasser lassen
			07JAN2011	YES	9:20	YES	18:05	Epi Pevaryl, friert immer wieder (3 Globuli Aluminium, 1 Pflaster Kentera) vom Urologen verschrieben gegen häufiges Wasser lassen

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	08JAN2011	YES	8:45	YES	19:05	tägl. Epi Pevaryl Creme
			09JAN2011	YES	7:45	YES	19:00	tägl. Epi Pevaryl Creme
			10JAN2011	YES	9:25	YES	18:30	tägl. Epi Pevaryl Creme
			11JAN2011	YES	9:55	YES	18:10	neues Pflaster kentera gegen zu oft Wasserlassen
			12JAN2011	YES	8:30			
			12JAN2011	YES		YES	18:25	tägl. Epi Pevaryl Creme
			13JAN2011	YES	9:30	YES	18:00	
			14JAN2011	YES	6:55	YES	19:15	Blasen Pflaster Kentera gegen zu häufiges Wasser lassen
			15JAN2011	YES	8:45	YES	19:00	
			16JAN2011	YES	7:55	YES	18:30	3 Globuli Alumina Hohe Potenz gegeben
			17JAN2011	YES	7:08	YES	18:20	
			18JAN2011	YES	8:40	YES	17:35	Blasen Pflaster Kentera gegen zu häufiges Wasser lassen.
			19JAN2011	YES	7:45	YES	18:42	5 Min. Kopfschmerzen (starkes Stechen) rechte Kopfhälfte oben (Gehirnrinde)
			20JAN2011	YES	8:10	YES	19:45	
			21JAN2011	YES	7:45	YES	19:25	Blasenpflaster Kentera 2x tägl. Epi Pevaryl Creme
			22JAN2011	YES	7:10	YES	18:55	
			23JAN2011	YES	7:50	YES	19:55	
			24JAN2011	YES	7:50	YES	18:50	
			25JAN2011	YES	8:00	YES	18:20	Blasenpflaster Kentera gegen zuviel Wasser lassen
			26JAN2011	YES	7:15	YES	19:50	Ciproflox-Ct 500mg gegen Blasenentzündung 2x1 Tabl. tägl.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	27JAN2011	YES	8:30	YES	18:50	1 Tabl. Ciproflox morgens, 1 Tabl. Ciproflox abends
			28JAN2011	YES	8:45	YES	19:30	1 Tabl. Ciproflox morgens, 1 Tabl. Ciproflox abends
			29JAN2011	YES	8:06	YES	17:50	1 Tabl. Ciproflox morgens, 1 Tabl. Ciproflox abends
			30JAN2011	YES	6:30	YES	19:10	tägl. Epi-Pevaryl Creme, 2x wöchentlich Kentera Blasenpflaster Di+Fr.
			31JAN2011	YES	7:05	YES	18:50	
			01FEB2011	YES	7:10	YES	20:45	
			02FEB2011	YES	7:10	YES	19:06	
			03FEB2011	YES	7:15	YES	19:00	
			04FEB2011	YES	7:00	YES	21:30	
			05FEB2011	YES	9:25	YES	18:45	
			06FEB2011	YES	8:08	YES	19:10	
			07FEB2011	YES	7:45	YES	18:55	
			08FEB2011	YES	8:15	YES	18:15	tägl. Epi Pevaryl-Creme gegen Fußpilz, Di./fr. 2x wöchentlich Kentera-Pflaster gegen häufiges Wasserlassen.
			09FEB2011	YES	9:05	YES	18:15	
			10FEB2011	YES	8:00	YES	18:30	
			11FEB2011	YES	7:40	YES	17:50	
			12FEB2011	YES	8:00	YES	18:10	
			13FEB2011	YES	7:38	YES	18:45	
			14FEB2011	YES	7:35	YES	19:30	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	15FEB2011	YES	7:30	YES	18:25	
			16FEB2011	YES	7:07	YES	19:00	
			17FEB2011	YES	7:15	YES	18:45	tägl. Epi Pevaryl-Creme gegen Fußpilz, Di+Fr. Kentera-Pflaster gegen häufiges Wasserlassen
			18FEB2011	YES	8:40	YES	18:15	
			19FEB2011	YES	6:40	YES	18:20	
			20FEB2011	YES	7:45	YES	19:00	
			21FEB2011	YES	9:35	YES	19:30	
			22FEB2011	YES	8:25	YES	21:15	
			23FEB2011	YES	7:50	YES	18:10	
			24FEB2011	YES	8:00	YES	19:00	
			25FEB2011	YES	7:40	YES	18:25	
			26FEB2011	YES	7:45	YES	19:00	tägl. Epi Pevaryl Creme, Di+Fr. Kentera-Pflaster gegen häufiges Wasserlassen
			27FEB2011	YES	7:33	YES	18:00	
			28FEB2011	YES	8:07	YES	18:30	
			01MAR2011	YES	7:40	YES	18:45	
			02MAR2011	YES	7:50	YES	19:00	
			03MAR2011	YES	8:00	YES	18:30	
			04MAR2011	YES	8:30	YES	18:35	
			05MAR2011	YES	8:00	YES	19:25	
			06MAR2011	YES	7:25	YES	18:55	
			07MAR2011	YES	8:00	YES	19:00	tägl. Epi Pevaryl Creme, 3 Globuli Alumina hohe Potenz, Di+Fr. Kentera-Pflaster gegen häufiges Wasserlassen

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	08MAR2011	YES	8:00	YES	19:00	
			09MAR2011	YES	8:30	YES	18:00	
			10MAR2011	YES	8:07	YES	18:20	
			11MAR2011	YES	8:25	YES	17:40	
			12MAR2011	YES	7:25	YES	17:40	
			13MAR2011	YES	7:00	YES	18:30	
			14MAR2011	YES	7:30	YES	17:50	
			15MAR2011	YES	7:40	YES	18:30	
			16MAR2011	YES	8:40	YES	18:00	tägl. Epi Pevaryl gegen Fußpilz, Di+Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			17MAR2011	YES	7:45	YES	18:25	
			18MAR2011	YES	8:30	YES	18:40	
			19MAR2011	YES	8:08	YES	18:35	
			20MAR2011	YES	7:30	YES	18:30	heute öfters gefroren
			21MAR2011	YES	7:45			
			21MAR2011	NO		YES	18:05	Di. + Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			22MAR2011	YES	7:40	YES	18:25	
			23MAR2011	YES	7:50	YES	18:30	
			24MAR2011		8:00		18:35	
			25MAR2011	YES	9:00	YES	23:10	
			26MAR2011	YES	7:20	YES	18:35	
			27MAR2011	YES	8:55		18:45	
			28MAR2011	YES	7:00	YES	22:30	
			29MAR2011	YES	8:20	YES	19:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	30MAR2011	YES	7:25	YES	18:30	Di. + Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			31MAR2011	YES	8:30	YES	18:25	
			01APR2011	YES	8:50	YES	18:10	
			02APR2011	YES	7:35	YES	19:45	
			03APR2011	YES	8:08	YES	18:45	4 Globuli Aluminium hohe Dosis gegen Schwächegefühl und Müdigkeit
			04APR2011	YES	7:00	YES	18:45	
			05APR2011	YES	8:20	YES	19:00	
			06APR2011	YES	8:05	YES	18:45	
			07APR2011	YES	17:05	YES	22:00	Tabletten wurden wg. Ausflug später genommen
			08APR2011	YES	7:48	YES	17:30	Di. + Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			09APR2011	YES	3:00	YES	23:00	
			10APR2011	YES	8:45	YES	19:30	
			11APR2011	YES	8:05	YES	19:00	
			12APR2011	YES	7:15	YES	18:00	
			13APR2011	YES	7:45	YES	18:30	
			14APR2011	YES	7:10	YES	18:00	
			15APR2011	YES	8:45	YES	19:45	
			16APR2011	YES	7:55	YES	18:20	Friert zur Zeit
			17APR2011	YES	7:20	YES	19:00	Di. + Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			18APR2011	YES	7:30	YES	18:25	Zur Zeit ständiges Frieren innerlich
			19APR2011	YES	7:40	YES	18:40	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	20APR2011	YES	7:40	YES	18:15	
			21APR2011	YES	7:01	YES	18:03	Im Moment geht es ganz gut, kein Frieren mehr
			22APR2011	YES	7:45	YES	18:15	
			23APR2011		7:45	YES	18:30	
			24APR2011	YES	8:00	YES	18:06	
			25APR2011	YES	7:35	YES	18:20	
			26APR2011	YES	8:20	YES	18:15	Di. + Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			27APR2011	YES	11:20	YES	20:25	
			28APR2011	YES	8:45	YES	18:10	
			29APR2011	YES	7:35	YES	19:10	
			30APR2011	YES	8:10	YES	17:30	3 Globuli Alumina XM
			01MAY2011	YES	7:35	YES	19:25	
			02MAY2011	YES	8:30	YES	18:30	
			03MAY2011	YES	7:05	YES	21:00	
			04MAY2011	YES	7:05		20:30	
			05MAY2011	YES	7:20	YES	18:15	Di. + Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			06MAY2011	YES	7:25	YES	18:50	
			07MAY2011	YES	7:30	YES	19:00	
			08MAY2011	YES	7:45	YES	19:45	
			09MAY2011	YES	8:45	YES	19:07	
			10MAY2011	YES	7:40	YES	18:05	
			11MAY2011	YES	8:27	YES	18:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	12MAY2011	YES	8:10	YES	18:03	Heute zitterig + öfters frieren, 3 Globuli Alumina hohe Potenz gegeben.
			13MAY2011	YES	7:30	YES	18:05	
			14MAY2011	NO		YES	19:20	Di. + Fr. Kentera-Pflaster gegen zu häufiges Wasserlassen
			15MAY2011	YES	10:35	YES	18:00	
			16MAY2011	YES	7:23	YES	19:15	
			17MAY2011	YES	7:50	YES	18:05	
			18MAY2011	YES	7:15	YES	17:45	
			19MAY2011	YES	7:10	YES	21:15	
			20MAY2011	YES	8:30	YES	18:22	
			21MAY2011	YES	7:20	YES	18:40	
			22MAY2011	YES	7:56	YES	18:53	
			23MAY2011	YES	7:48	YES	19:00	Di. + Fr. Kenterapflaster, zur Zeit friert mein Mann immer wieder
			24MAY2011	YES	7:45	YES	20:15	
			25MAY2011	YES	7:45	YES	19:00	
			26MAY2011	YES	7:15	YES	19:15	1 Tablette Dermatin + Batrafen Gel gegen Fußnagelpilz
			27MAY2011	YES	8:23	YES	18:05	
			28MAY2011	YES	8:00	YES	18:15	
			29MAY2011	YES	7:45	YES	19:10	
			30MAY2011	YES	7:00	YES	18:00	
			31MAY2011	YES	7:32	YES	18:20	
			01JUN2011	YES	8:12	YES	18:00	Di. + Fr. Kenterapflaster

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	02JUN2011	YES	7:00	YES	18:25	1 Tabl. Dermatin + Batrafen Gel gegen Fußnagelpilz
			03JUN2011	YES	7:20	YES	18:27	1 Tabl. Dermatin + Batrafen Gel gegen Fußnagelpilz
			04JUN2011	YES	7:30	YES	18:05	1 Tabl. Dermatin + Batrafen Gel gegen Fußnagelpilz
			05JUN2011	YES	8:05	YES	18:05	
			06JUN2011	YES	8:00	YES	18:10	
			07JUN2011	YES	7:35	YES	18:20	
			08JUN2011	YES	7:00	YES	18:20	
			09JUN2011	YES	7:30	YES	18:40	
			10JUN2011	YES	7:55	YES	17:55	Wie vor
			11JUN2011	YES	7:45	YES	18:39	
			12JUN2011	YES	7:35	YES	18:00	
			13JUN2011	YES	9:00	YES	18:00	
			14JUN2011	YES	7:15	YES	17:50	
			15JUN2011	YES	7:30	YES	18:25	
			16JUN2011	YES	7:15	YES	18:20	
			17JUN2011	YES	7:35	YES	19:00	
			18JUN2011	YES	8:50	YES	18:30	
			19JUN2011	YES	8:25	YES	18:50	Wie vor
			20JUN2011	YES	8:30	YES	18:30	9 Kügelchen Alumina (Alumina) geringe Potenz gegeben <30 (9 Globuli)
			21JUN2011	YES	7:50	YES	18:25	
			22JUN2011	YES	7:10	YES	18:30	
			23JUN2011	YES	7:30	YES	18:05	
			24JUN2011	YES	8:10	YES	18:45	
			25JUN2011	YES	7:55	YES	18:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	26JUN2011	YES	9:00	YES		
			27JUN2011	YES	8:10	YES	19:45	
			28JUN2011	YES	6:55	YES	18:07	Medikamente + Pflaster wie vor
			29JUN2011	YES	7:35	YES	18:15	Medikamente + Pflaster wie vor
			30JUN2011	YES	10:15	YES	18:00	
			01JUL2011	YES	9:20	YES	19:00	
			02JUL2011	YES	8:00	YES	21:20	
			03JUL2011	YES	8:20	YES	19:50	
			04JUL2011	YES	7:55	YES	18:40	
			05JUL2011	YES	8:12	YES	18:00	
			06JUL2011	YES	8:15	YES	19:45	
			07JUL2011	YES	6:45	YES	17:55	Friert im Moment wieder alle 2 Std.
			08JUL2011	YES	10:07	YES	18:55	9 Globuli Alumina (C 200 gegeben), Medikamente ansonsten wie vor
			09JUL2011	YES	8:50	YES	18:00	Medikamente ansonsten wie vor und 3 Teelöffel Schwedenbitter im Apfel- oder Traubensaft gegeben.
			10JUL2011	YES	9:35	YES	17:45	Medikamente ansonsten wie vor und 3 Teelöffel Schwedenbitter im Apfel- oder Traubensaft gegeben.
			11JUL2011	YES	8:35	YES	19:15	Frierzustand ist vorbei. Wir waren auch tägl. beim Schwimmen, es tat sehr gut!
			12JUL2011	YES	8:50	YES	19:30	Frierzustand ist vorbei. Wir waren auch tägl. beim Schwimmen, es tat sehr gut!
			13JUL2011	YES	8:30	YES	19:00	Im Moment friert mein Mann nicht, nachdem er 3 Teel. Schwedenbitter im Saft eingenommen hat (tägl.)

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	023	4	14JUL2011	YES	7:45	YES	18:20	Im Moment friert mein Mann nicht, nachdem er 3 Teel. Schwedenbitter im Saft eingenommen hat (tägl.)
			15JUL2011	YES	7:30	YES	10:35	
			16JUL2011	YES	8:10	YES	18:50	Di. + Fr. Kentera-Pflaster 1x tägl. 1 Tablette Dermatin wg. Fußpilz, Medikamente wie vor
			17JUL2011	YES	9:30	YES	18:10	Tägl. 3 Teel. Schwedenbitter
			18JUL2011	YES	7:20			
			14AUG2011	YES	7:30	YES	18:35	
	027	20		YES	8:00	YES	19:30	war sehr müde, aber war sehr froh vom von den guten Nachricht_müde
				YES	8:00	YES	20:00	schlafe tief u. lange
				YES	8:00	YES	20:00	schlafe tief u. lange
				YES	8:00	YES	20:15	schlafe tief u. lange
				YES	8:00	YES	20:00	schlafe tief u. lange
				YES	8:00	YES	20:00	schlafe tief u. lange
				YES	8:00	YES	20:00	schlafe tief u. lange
				YES	8:00	YES	20:00	schlafe tief u. lange
				YES	8:00	YES	20:00	geht besser
				YES	8:30	YES	18:00	etwas besser
				YES	8:30	YES	18:00	etwas besser
				YES	9:00	YES	18:00	etwas besser
				YES	8:30	YES	18:15	etwas besser
				YES	8:30	YES	18:00	etwas besser

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20		YES	8:15	YES	18:00	etwas besser
				YES	8:30	YES	18:00	gleich bleibend
				YES	8:30	YES	18:15	Vergessenheit wieder stark
				YES	8:00	YES	18:00	Vergessenheit wieder stark
				YES	8:30	YES	18:30	Vergessenheit bleibt
				YES	8:30	YES	18:30	Vergessenheit bleibt
				YES	18:00	YES	18:30	Vergessenheit bleibt
				YES	18:00	YES	18:30	sehr arg
				YES	8:30	YES	18:45	sehr arg
				YES	8:30	YES	18:30	sehr arg
				YES	8:30	YES	18:30	sehr arg
				YES	8:15	YES	18:30	sehr arg
				YES	8:30	YES	18:30	sehr arg
			17OCT2010	YES	8:15			
			18OCT2010	YES				
			22OCT2010	YES	8:00	YES	19:00	
			23OCT2010	YES	7:00	YES	20:00	Zeit ungewiss am Abend
			24OCT2010	YES	8:45	YES	19:00	Keine Besserung eingetreten
			25OCT2010	YES	7:30	YES	19:00	Keine Besserung eingetreten
			26OCT2010	YES	8:00	YES	20:00	Keine Besserung eingetreten
			27OCT2010	YES	8:00	YES	20:00	Keine Besserung eingetreten
			28OCT2010	YES	8:00	YES	20:00	Keine Besserung eingetreten
			29OCT2010	YES	8:00	YES	20:00	Keine Besserung eingetreten
			30OCT2010	YES	8:00	YES	20:00	keine Verbesserung, auch keine Nebenwirkungen
			31OCT2010	YES	8:00	YES	20:00	keine Verbesserung, auch keine Nebenwirkungen

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20	01NOV2010	YES	8:30	YES	20:00	keine Verbesserung, auch keine Nebenwirkungen
			02NOV2010	YES	8:00	YES	22:00	sehr traurig, habe den ganzen Tag geweint, Familie
			03NOV2010	YES	8:00	YES	20:00	sehr traurig, habe den ganzen Tag geweint, Familie
			04NOV2010	YES	8:00	YES	20:00	Zustand gleich geblieben
			05NOV2010	YES	8:00	YES	20:00	Vergesslichkeit, keine Besserung
			06NOV2010	YES	8:00	YES	20:00	Vergesslichkeit, keine Besserung
			07NOV2010	YES	8:00	YES	20:00	Vergesslichkeit, keine Besserung
			08NOV2010	YES	8:00	YES	20:00	keine Besserung eingetreten
			09NOV2010	YES	8:00	YES	20:00	keine Besserung eingetreten und schlafe jeden Tag bis Mittag und bin immer noch müde
			10NOV2010	YES	8:00	YES	20:00	keine Besserung eingetreten und schlafe jeden Tag bis Mittag und bin immer noch müde
			11NOV2010	YES	8:00	YES	20:15	sehr traurig weil ich wieder Schlüssel verlegt habe
			12NOV2010	YES	8:00	YES	20:00	Krach mit Erika
			13NOV2010	YES	8:00	YES	20:00	Normaler Tag
			14NOV2010	YES	8:00	YES	20:00	schöner Tag, positiv
			15NOV2010	YES	8:00	YES	20:00	Katastrophentag - Patientenbuch verlegt
			16NOV2010	YES	8:00			habe das Buch wieder, Daniel hat es im Abfallk. gelegt in einer alten Zeitung.
			18NOV2010	YES	8:00	YES	20:00	Ein langer Tag für, aber konnte ganz zufrieden nach Hause gehen
			19NOV2010	YES	8:00	YES	20:00	Habe mein Arbeitszeugnis gesucht + immer noch nicht gefunden
			20NOV2010	YES	8:15	YES	20:00	s. ist mir nicht gut gegangen, war sehr unruhig

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20	21NOV2010	YES	8:00	YES	20:00	Zeugnisse gefunden, schlafe sehr lange
			22NOV2010	YES	8:00	YES	20:00	m. heute geht es mir gut
			23NOV2010	YES	8:00	YES	20:00	bin rundum zufrieden
			24NOV2010	YES	8:00	YES	20:00	Ich schlafe sehr lange v. 23:00 bis 11- oder 12:00, ich frage schon warum
			25NOV2010	YES	8:00	YES	20:00	Es war ein langer Tag_ trotzdem ging es mir gut
			26NOV2010	YES	8:30	YES	20:00	Ich schlafe immer so lange das ist nicht normal warum???
			27NOV2010	YES	8:00	YES	20:00	So olala
			28NOV2010	YES	8:00	YES	20:00	So leer und traurig
			29NOV2010	YES	8:00	YES	20:00	Ging mir wieder besser
			30NOV2010	YES	8:00	YES	20:00	Ich schlafe + schlafe den ganzen Tag
			01DEC2010	YES	8:00		20:00	Ich schlafe + schlafe den ganzen Tag
			02DEC2010	YES	8:00	YES	20:00	Pflaster vergessen + schlafe ganzen Tag u. sehr tief
			03DEC2010	YES	8:30		20:00	Pflaster vergessen + schlafe ganzen Tag u. sehr tief, ist schon nicht normal
			04DEC2010	YES	8:00	YES	20:00	u. ich bin sehr sehr traurig wegen m. Geschwister
			05DEC2010	YES	8:15	YES	20:00	u. ich bin sehr sehr traurig wegen m. Geschwister
			06DEC2010	YES	8:00	YES	20:00	mit Schlafen immer unverändert
			07DEC2010	YES	8:20	YES	19:00	mit Schlafen immer unverändert
			08DEC2010	YES	8:30	YES	19:00	mit Schlafen immer unverändert, aber es geht besser, freue mit darüber
			09DEC2010	YES	8:30	YES	19:00	mit Schlafen immer unverändert, aber es geht besser, freue mit darüber

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20	10DEC2010	YES	8:30	YES	19:30	mit Schlafen immer unverändert, aber es geht besser, freue mit darüber
			11DEC2010	YES	9:00	YES	19:00	nicht so gut
			12DEC2010	YES	8:00	YES	19:00	ist schon eklig, wenn man mich beklaut, macht mich schon traurig
			13DEC2010	YES	8:00	YES	19:00	
			14DEC2010	YES	8:00	YES	19:00	hatte einen guten Tag
			15DEC2010	YES	8:00	YES	19:00	schöner Tag
			16DEC2010	YES	8:00	YES	19:00	habe mich verwöhnt, war ganz zufrieden
			17DEC2010	YES	8:00	YES	19:00	ich habe sehr lang geschlafen, warum frage ich mich
			18DEC2010	YES	8:00	YES	19:00	ich habe sehr lang geschlafen, warum frage ich mich
			19DEC2010	YES	8:00	YES	19:00	ich habe sehr lang geschlafen, warum frage ich mich
			20DEC2010	YES		YES	19:00	ich habe sehr lang geschlafen, warum frage ich mich
			21DEC2010	YES	8:00	YES	19:00	ich habe sehr lang geschlafen, warum frage ich mich
			22DEC2010	YES	8:00	YES	19:00	ich habe sehr lang geschlafen, warum frage ich mich
			23DEC2010	YES	8:00	YES	19:00	ich habe sehr lang geschlafen, warum frage ich mich
			24DEC2010	YES	8:00	YES	19:00	traurig
			25DEC2010	YES	8:00		19:00	besser

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20	26DEC2010	YES	8:00	YES	19:00	besser
			27DEC2010	YES	8:00	YES	19:00	traurig wegen Familie
			28DEC2010	YES	8:00	YES	19:00	traurig wegen Familie
			29DEC2010	YES	8:00	YES	19:00	traurig wegen Familie
			30DEC2010	YES	8:00	YES	19:00	besser
			31DEC2010	YES	8:00	YES	19:00	Weihnachten schlecht
			01JAN2011	YES	8:00	YES	19:00	Weihnachten schlecht
			02JAN2011	YES	8:00	YES	20:00	es waren die schlimmsten Weihnachten
			03JAN2011	YES	8:00	YES	20:00	ich denke seit ich weiß, dass sie es gibt
			04JAN2011	YES	8:00	YES	20:00	traurig
			05JAN2011	YES	8:00	YES	20:00	traurig
			06JAN2011	YES	8:15	YES	20:00	
			07JAN2011	YES	8:00	YES	20:00	
			08JAN2011	YES	8:00	YES	20:00	habe ganze Nach n. schlafen können
			09JAN2011	YES	8:00	YES	20:15	u. heute auch nicht
			10JAN2011	YES	8:00	YES	20:00	geht besser
			11JAN2011	YES	8:00	YES	20:15	geht mir besser
			12JAN2011	YES	8:00	YES	20:00	geht mir gut
			13JAN2011	YES	8:00	YES	20:00	geht mir gut
			14JAN2011	YES	8:15	YES	20:00	geht mir sehr gut
			15JAN2011	YES	8:00	YES	20:00	geht mir sehr gut
			16JAN2011	YES	8:00	YES	20:00	geht mir sehr gut
			17JAN2011	YES	8:00	YES	20:00	geht mir sehr gut
			18JAN2011	YES	8:00	YES	20:00	geht mir sehr gut
			19JAN2011	YES	8:00	YES	20:10	geht mir sehr gut

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20	20JAN2011	YES	8:00	YES	20:00	
			21JAN2011	YES	8:00	YES	20:10	
			22JAN2011	YES	8:20	YES	20:00	
			23JAN2011	YES	8:00	YES	20:15	
			24JAN2011	YES	8:00	YES	20:00	
			13APR2011	YES	8:00	YES	20:00	gut
			14APR2011	YES	8:00	YES	20:00	gut
			15APR2011	YES	8:00	YES	20:00	gut
			16APR2011	YES	8:00	YES	20:00	gut
			16APR2011	YES	8:00	YES	20:00	gut
			17APR2011	YES	8:00	YES	20:00	sehr müde
			18APR2011	YES	8:00	YES	20:00	sehr müde
			19APR2011	YES	8:00	YES	20:00	sehr müde
			20APR2011	YES	8:00	YES	20:00	gut
			21APR2011	YES	8:00	YES	20:00	müde
			22APR2011	YES	8:00	YES	20:00	müde
			23APR2011	YES	8:00		20:00	gut
			24APR2011	YES	8:00		20:00	gut
			25APR2011	YES	8:00		20:00	gut
			26APR2011	YES	8:00	YES	20:00	gut
			27APR2011	YES	8:00	YES	20:00	gut
			28APR2011	YES	8:00	YES	20:00	gut
			29APR2011	YES	8:00	YES	20:00	gut
			30APR2011	YES	8:00	YES	20:00	normal
			01MAY2011	YES	8:00	YES	20:00	normal

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ACI-91	027	20	02MAY2011	YES	8:00	YES	20:00	normal
			03MAY2011	YES	8:00	YES	20:00	normal
			04MAY2011	YES	8:00	YES	20:00	normal
			05MAY2011	YES	8:00	YES	20:00	normal
			06MAY2011	YES	8:00	YES	20:00	normal
			07MAY2011	YES	8:00	YES	20:00	normal
			08MAY2011	YES	8:00	YES	20:00	normal
			09MAY2011	YES	8:00	YES	20:00	gut
			10MAY2011	YES	8:00	YES	20:00	gut
			11MAY2011	YES	8:00	YES	20:00	gut
			12MAY2011	YES	8:00	YES	20:00	gut
			13MAY2011	YES	8:00	YES	20:00	gut
			14MAY2011	YES	8:00	YES	20:00	gut
			15MAY2011	YES	8:00	YES	20:00	gut
			16MAY2011	YES	8:00	YES	20:00	müde
			17MAY2011	YES	8:00	YES	20:00	müde
			18MAY2011	YES	8:00	YES	20:00	müde
			19MAY2011	YES	8:00	YES	20:00	müde
			20MAY2011	YES	8:00	YES	20:00	müde
			21MAY2011	YES	8:00	YES	20:00	müde
			22MAY2011	YES	8:00	YES	20:00	gut
			23MAY2011	YES	8:00	YES	20:00	gut
			24MAY2011	YES	8:00	YES	20:00	gut
			25MAY2011	YES	8:00	YES	20:00	gut
			26MAY2011	YES	8:00	YES	20:00	gut

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20	27MAY2011	YES	8:00	YES	20:00	gut
			28MAY2011	YES	8:00	YES	20:00	gut
			29MAY2011	YES	8:00	YES	20:00	gut
			30MAY2011	YES	8:00	YES	20:00	viel geschlafen
			31MAY2011	YES	8:00	YES	20:00	viel geschlafen
			01JUN2011	YES	8:00	YES	20:00	viel geschlafen
			02JUN2011	YES	8:00	YES	20:00	gut
			03JUN2011	YES	8:00	YES	20:00	gut
			04JUN2011	YES	8:00	YES	20:00	gut
			05JUN2011	YES	8:00	YES	20:00	gut
			06JUN2011	YES	8:00	YES	20:00	gut
			07JUN2011	YES	8:00	YES	20:00	gut
			08JUN2011	YES	8:00	YES	20:00	gut
			09JUN2011	YES	8:00	YES	20:00	traurig
			10JUN2011	YES	8:00	YES	20:00	traurig
			11JUN2011	YES	8:00	YES	20:00	traurig
			12JUN2011	YES	8:00	YES	20:00	gut
			13JUN2011	YES	8:00	YES	20:00	gut
			14JUN2011	YES	8:00	YES	20:00	
			15JUN2011	YES	8:00	YES	20:00	
			16JUN2011	YES	8:00	YES	20:00	
			17JUN2011	YES	8:00	YES	20:00	
			18JUN2011	YES	8:00	YES	20:00	
			19JUN2011	YES	8:00	YES	20:00	
			20JUN2011	YES	8:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	027	20	21JUN2011	YES	8:00	YES	20:00	
			22JUN2011	YES	8:00	YES	20:00	
			23JUN2011	YES	8:00	YES	20:00	normal
			24JUN2011	YES	8:00	YES	20:00	normal
			25JUN2011	YES	8:00	YES	20:00	normal
			26JUN2011	YES	8:00	YES	20:00	normal
			27JUN2011	YES	8:00	YES	20:00	normal
			28JUN2011	YES	8:00	YES	20:00	normal
			29JUN2011	YES	8:00	NO	20:00	Kopfweh
			30JUN2011	YES	8:00	YES	20:00	normal
			01JUL2011	YES	8:00	YES	20:00	normal
			02JUL2011	YES	8:00	YES	20:00	gut
			03JUL2011	YES	8:00	YES	20:00	gut
			04JUL2011	YES	8:00	YES	20:00	gut
			05JUL2011	YES	8:00	YES	20:00	gut
			06JUL2011	YES	8:00	YES		
	030	8	25MAR2010	YES	11:50	YES	18:10	
			26MAR2010	YES	8:40	YES	17:55	
			27MAR2010	YES	8:35	YES	17:55	
			28MAR2010	YES	8:40	YES	19:00	
			29MAR2010	YES	8:50	YES	17:35	
			30MAR2010	YES	8:25	YES	17:55	
			31MAR2010	YES	8:40	YES	18:15	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	01APR2010	YES	8:35		17:00	nach dem Frühstück Schwindelgefühl - trockener Mund - kalt, Puls: 91, BD: 145/71, 63, abends: dto.
			02APR2010	YES	8:45	YES	19:30	Heute: Mund trocken
			03APR2010	YES	8:40	YES	19:10	nach der Einnahme - trockenen Mund - morgens + abends
			04APR2010	YES	8:50	YES	18:40	½ Std nach Einnahme wird es kalt u. hält ca. 3 Std an, dann wieder normal
			05APR2010	YES	8:45	YES	17:40	1 Std nach Einnahme wieder schwindelig: ca. 4 Std. BD: 136/59/66
			06APR2010	YES	8:40	YES	19:35	wie gestern. BD: 133/77/78., abends: normal
			07APR2010	YES	8:55	YES	17:55	heute leichte Schmerzen i. Kopf etwas schwindelig
			08APR2010	YES	8:45	YES	17:55	morgens: nach Einnahme ca. ½ Std. später Schwindel "wie betrunken". 11:00 h wieder normal
			09APR2010	YES	8:40	YES	18:40	BD: 122/64/72 morgens: wie gestern
			10APR2010	YES	8:45	YES	18:00	morgens: Schwindel, abends: normal
			11APR2010	YES	8:55	YES	18:00	wie gestern
			12APR2010	YES	8:45	YES	17:45	morgens: Schwindel, BD: 127/65/65
			13APR2010	YES	8:45	YES	18:20	morgens: Schwindel
			14APR2010	YES	8:45	YES	19:05	morgen sehr schlecht, BD 127/67/69
			15APR2010	YES	8:45	YES	18:00	morgen sehr schlecht (Schwindel)
			16APR2010	YES	8:50	YES	17:25	dto.
			17APR2010	YES	8:35	YES	18:00	dto.
			18APR2010	YES	6:50		18:05	dto.
			19APR2010	YES	8:45	YES	18:50	morgens sehr schlecht Schwindel, BD: 125/75/89

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	20APR2010	YES	8:40	YES	17:40	morgens Schwindel
			21APR2010	YES	8:40			
			21APR2010			YES	17:45	
			22APR2010	YES	8:40	YES	17:40	
			23APR2010	YES	8:40	YES	17:30	
			24APR2010	YES	8:40	YES	17:40	
			25APR2010	YES	8:40	YES	18:10	
			26APR2010	YES	8:00	YES	17:50	
			27APR2010	YES	8:30	YES	16:50	
			28APR2010	YES	8:40	YES	18:05	
			29APR2010	YES	8:55	YES	19:00	
			30APR2010	YES	8:45	YES	18:05	
			01MAY2010	YES	9:05	YES	17:55	
			02MAY2010	YES	9:05	YES	17:55	
			03MAY2010	YES	8:50	YES	17:55	
			04MAY2010	YES	8:45	YES	17:55	
			05MAY2010	YES	8:50	YES	17:40	
			06MAY2010	YES	8:45	YES	18:05	
			07MAY2010	YES	8:45	YES	17:35	
			08MAY2010	YES	8:50	YES	17:45	
			09MAY2010	YES	8:50	YES	18:30	
			10MAY2010	YES	8:50	YES	18:10	
			11MAY2010	YES	9:05	YES	18:05	
			12MAY2010	YES	8:55	YES	18:00	
			13MAY2010	YES	8:55	YES	18:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	14MAY2010	YES	8:50	YES	17:25	
			15MAY2010	YES	8:55	YES	17:50	
			16MAY2010	YES	8:45	YES	18:05	
			17MAY2010	YES	8:50	YES	17:40	
			18MAY2010	YES	8:40	YES	18:15	
			19MAY2010	YES	9:30	YES	18:05	
			20MAY2010	YES	9:30	YES	17:45	
			21MAY2010	YES	9:05	YES	18:00	
			22MAY2010	YES	8:55	YES	19:10	
			23MAY2010	YES	8:55	YES	19:15	
			24MAY2010	YES	8:50	YES	18:15	
			25MAY2010	YES	8:45	YES	18:15	
			26MAY2010	YES	8:45	YES	18:05	
			27MAY2010	YES	8:45	YES	17:50	
			28MAY2010	YES	8:50	YES	18:10	
			29MAY2010	YES	8:45	YES	18:10	
			30MAY2010	YES	9:00	YES	17:25	
			31MAY2010	YES	8:45	YES	17:25	
			01JUN2010	YES	8:50	YES	18:30	
			02JUN2010	YES	8:45	YES	17:30	
			03JUN2010	YES	8:55	YES	18:05	
			04JUN2010	YES	7:45	NO		vergessen, absichtlich wg. Alkoholkonsum
			05JUN2010	YES	7:45	YES	17:00	
			06JUN2010	YES	9:10	YES	17:35	
			07JUN2010	YES	8:50	YES	17:50	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	08JUN2010	YES	8:40	YES	17:45	
			09JUN2010	YES	8:45	YES	17:35	
			10JUN2010	YES	8:30	YES	19:45	
			11JUN2010	YES	8:45	YES	17:45	
			12JUN2010	YES	9:00	YES	17:20	
			13JUN2010	YES	8:30	YES	20:30	
			14JUN2010	YES	8:40	YES	18:05	
			15JUN2010	YES	8:40	YES	18:30	
			16JUN2010	YES	8:50	YES	18:05	
			17JUN2010	YES	7:25			
			18JUN2010	YES	8:45	YES	17:35	
			19JUN2010	YES	8:40	YES	18:00	
			20JUN2010	YES	8:55	YES	18:30	
			21JUN2010	YES	8:40	YES	17:35	
			22JUN2010	YES	9:00	YES	18:00	
			23JUN2010	YES	8:35	YES	19:25	
			24JUN2010	YES	6:45	YES	22:40	
			25JUN2010	YES	8:40	YES	17:30	
			26JUN2010	YES	8:55	YES	17:20	
			27JUN2010	YES	9:05	YES	18:00	
			28JUN2010	YES	8:50	YES	17:30	
			29JUN2010	YES	8:50	YES	17:40	
			30JUN2010	YES	8:45	YES	20:10	
			01JUL2010	YES	9:05	YES	18:00	
			02JUL2010	YES	8:45	YES	17:50	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	03JUL2010	YES	8:55	YES	17:55	
			04JUL2010	YES	8:50	YES	17:55	
			05JUL2010	YES	8:45	YES	17:50	
			06JUL2010	YES	8:50	YES	21:30	
			07JUL2010	YES	8:50	YES	17:30	
			08JUL2010	YES	8:50	YES	17:30	
			09JUL2010	YES	8:50	YES	17:10	
			10JUL2010	YES	8:55	YES	17:20	
			11JUL2010	YES	8:55	YES	17:10	
			12JUL2010	YES	8:55	YES	17:45	
			13JUL2010	YES	8:45	YES	18:45	
			14JUL2010	YES	8:45	YES	17:30	
			15JUL2010	YES	8:35	YES	17:50	
			16JUL2010	YES	8:50	YES	17:35	
			17JUL2010	YES	8:55	YES	22:10	
			18JUL2010	YES	8:50	YES	17:25	
			19JUL2010	YES	8:50	YES	20:45	
			20JUL2010	YES	8:55	YES	17:15	
			21JUL2010	YES	8:40	YES	17:10	
			22JUL2010	YES	8:30	YES	17:15	
			23JUL2010	YES	8:40	YES	17:10	
			24JUL2010	YES	8:40	YES	17:15	
			25JUL2010	YES	8:50	YES	17:10	
			26JUL2010	YES	8:50	YES	17:15	
			27JUL2010	YES	8:45	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	28JUL2010	YES	9:00	YES	17:15	
			29JUL2010	YES	8:35	YES	17:40	
			30JUL2010	YES	8:45	YES	17:10	
			31JUL2010	YES	8:55	YES	17:10	
			01AUG2010	YES	8:50	YES	17:15	
			02AUG2010	YES	8:20	YES	17:15	
			03AUG2010	YES	8:40	YES	21:10	
			04AUG2010	YES	8:35	YES	17:30	
			05AUG2010	YES	8:55	YES	17:40	
			06AUG2010	YES	8:45	YES	17:25	
			07AUG2010	YES	8:40	YES	17:30	
			08AUG2010	YES	9:05	YES	17:35	
			09AUG2010	YES	8:30	YES	17:40	
			10AUG2010	YES	8:45	YES	17:10	
			11AUG2010	YES	8:50	YES	17:15	
			12AUG2010	YES	8:20	YES	17:10	
			13AUG2010	YES	8:50	YES	18:30	
			14AUG2010	YES	9:00	YES	17:10	
			15AUG2010	YES	8:45	YES	17:15	
			16AUG2010	YES	8:55	YES	17:25	
			17AUG2010	YES	8:35	YES	17:25	
			18AUG2010	YES	8:45	YES	17:35	
			19AUG2010	YES	8:50	YES	18:45	
			20AUG2010	YES	8:40	YES	17:15	
			21AUG2010	YES	8:40	YES	19:50	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	22AUG2010	YES	8:55	YES	17:10	
			23AUG2010	YES	8:35	YES	17:15	
			24AUG2010	YES	8:40	YES	17:20	
			25AUG2010	YES	8:45	YES	18:05	
			26AUG2010	YES	8:50	YES	17:35	
			27AUG2010	YES	8:45	YES	18:30	
			28AUG2010	YES	8:55	YES	17:20	
			29AUG2010	YES	8:50	YES	19:15	
			30AUG2010	YES	8:50	YES	17:20	
			31AUG2010	YES	8:35	YES	17:15	
			01SEP2010	YES	8:45	YES	18:00	
			02SEP2010	YES	8:35	YES	17:10	
			03SEP2010	YES	7:45			
			03SEP2010			YES	17:20	
			04SEP2010	YES	9:05	YES	17:45	
			05SEP2010	YES	8:50	YES	17:30	
			06SEP2010	YES	8:30	YES	17:35	
			07SEP2010	YES	8:45	YES	16:45	
			08SEP2010	YES	9:05	YES	17:25	
			09SEP2010	YES	9:00	YES	17:15	
			10SEP2010	YES	8:20	YES	17:15	
			11SEP2010	YES	8:55	YES	17:15	
			12SEP2010	YES	9:05	YES	18:35	
			13SEP2010	YES	8:45	YES	17:15	
			14SEP2010	YES	7:30	YES	18:35	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	15SEP2010	YES	8:55	YES	17:30	
			16SEP2010	YES	8:40	YES	17:20	
			17SEP2010	YES	8:50	YES	17:20	
			18SEP2010	YES	8:35	YES	17:15	
			19SEP2010	YES	8:50	YES	18:40	
			20SEP2010	YES	8:50	YES	17:50	
			21SEP2010	YES	8:50	YES	21:00	
			22SEP2010	YES	8:55	YES	17:30	
			23SEP2010	YES	8:35	YES	17:15	
			24SEP2010	YES	8:35	YES	17:20	
			25SEP2010	YES	8:55	YES	17:35	
			26SEP2010	YES	8:55	YES	18:05	
			27SEP2010	YES	8:35	YES	17:15	
			28SEP2010	YES	8:50	YES	17:15	
			29SEP2010	YES	8:50	YES	17:35	
			30SEP2010	YES	8:40	YES	17:40	
			01OCT2010	YES	8:45	YES	17:25	
			02OCT2010	YES	8:50	YES	17:45	
			03OCT2010	YES	9:15	YES	20:20	
			04OCT2010	YES	8:35	YES	17:15	
			05OCT2010	YES	8:35	YES	17:25	
			06OCT2010	YES	8:35	YES	17:45	
			07OCT2010	YES	8:40	YES	17:15	
			08OCT2010	YES	8:45	YES	17:20	
			09OCT2010	YES	8:50	YES	17:15	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	10OCT2010	YES	8:55	YES	17:45	
			11OCT2010	YES	8:45	YES	17:25	
			12OCT2010	YES	8:35	YES	17:15	
			13OCT2010	YES	8:50	YES	20:25	
			14OCT2010	YES	7:20	YES	19:25	
			15OCT2010	YES	8:35	YES	18:45	
			16OCT2010	YES	7:45	YES	19:45	
			17OCT2010	YES	8:50	YES	17:55	
			18OCT2010	YES	6:40	YES	18:10	
			19OCT2010	YES	8:35	YES	17:40	
			20OCT2010	YES	8:30	YES	18:50	
			21OCT2010	YES	6:30	YES	17:25	
			22OCT2010	YES	8:50	YES	17:50	
			23OCT2010	YES	8:55	YES	19:00	
			24OCT2010	YES	9:05	YES	17:45	
			25OCT2010	YES	8:55	YES	17:30	
			26OCT2010	YES	8:50	YES	18:05	
			27OCT2010	YES	8:45	YES	17:25	
			28OCT2010	YES	8:35	YES	18:05	
			29OCT2010	YES	8:55	YES	17:15	
			30OCT2010	YES	8:45	YES	17:25	
			31OCT2010	YES	8:30	YES	18:30	
			01NOV2010	YES	8:45	YES	17:20	
			02NOV2010	YES	8:35	YES	18:30	
			03NOV2010	YES	7:40	YES	18:35	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	04NOV2010	YES	8:30	YES	17:15	
			05NOV2010	YES	8:45	YES	17:45	
			06NOV2010	YES	8:45	YES	19:00	
			07NOV2010	YES	7:45	YES	21:45	
			08NOV2010	YES	8:00	YES	18:05	
			09NOV2010	YES	8:55	YES	17:50	
			10NOV2010	YES	9:00	YES	17:15	
			11NOV2010	YES	8:55	YES	17:10	
			12NOV2010	YES	8:50	YES	17:10	
			13NOV2010	YES	8:45	YES	17:10	
			14NOV2010	YES	8:55	YES	17:15	
			15NOV2010	YES	8:50	YES	17:25	
			16NOV2010	YES	8:45	YES	17:35	
			17NOV2010	YES	8:45	YES	17:15	
			18NOV2010	YES	8:35	YES	17:20	
			19NOV2010	YES	8:50	YES	17:15	
			20NOV2010	YES	9:05	YES	17:20	
			21NOV2010	YES	9:05	YES	17:30	
			22NOV2010	YES	8:40	YES	17:15	
			23NOV2010	YES	8:50	YES	17:15	
			24NOV2010	YES	8:45	YES	18:15	
			25NOV2010	YES	9:05	YES	18:05	
			26NOV2010	YES	8:50	YES	17:20	
			27NOV2010	YES	8:50	YES	17:20	
			28NOV2010	YES	8:50	YES	17:55	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	29NOV2010	YES	8:45	YES	17:10	
			30NOV2010	YES	7:05	YES	17:15	
			01DEC2010	YES	8:50	YES	17:25	
			02DEC2010	YES	7:25			
			02DEC2010			YES	17:40	
			03DEC2010	YES	8:55	YES	17:35	
			04DEC2010	YES	8:45	YES	17:15	
			05DEC2010	YES	9:05	YES	18:00	
			06DEC2010	YES	8:55	YES	17:10	
			07DEC2010	YES	8:40	YES	23:00	
			08DEC2010	YES	8:30	YES	17:15	
			09DEC2010	YES	8:15	YES	17:15	
			10DEC2010	YES	7:45	YES	17:25	
			11DEC2010	YES	8:55	YES	17:20	
			12DEC2010	YES	9:10	YES	17:15	
			13DEC2010	YES	8:40	YES	17:15	
			14DEC2010	YES	9:05	YES	17:15	
			15DEC2010	YES	8:55	YES	17:10	
			16DEC2010	YES	9:00	YES	17:25	
			17DEC2010	YES	8:45	YES	17:15	
			18DEC2010	YES	8:50	YES	17:10	
			19DEC2010	YES	9:10	YES	17:20	
			20DEC2010	YES	8:40	YES	18:25	
			21DEC2010	YES	8:50	YES	17:35	
			22DEC2010	YES	8:40	YES	18:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	23DEC2010	YES	8:55	YES	17:50	
			24DEC2010	YES	9:10	YES	17:20	
			25DEC2010	YES	9:05	YES	17:25	
			26DEC2010	YES	9:25	YES	18:05	
			27DEC2010	YES	8:45	YES	17:25	
			28DEC2010	YES	10:05	YES	18:55	
			29DEC2010	YES	8:50	YES	17:05	
			30DEC2010	YES	8:55	YES	17:35	
			31DEC2010	YES	8:50	YES	18:10	
			01JAN2011	YES	10:20	YES	17:15	
			02JAN2011	YES	8:50	YES	17:40	
			03JAN2011	YES	8:45	YES	17:35	
			04JAN2011	YES	9:05	YES	17:15	
			05JAN2011	YES	9:00	YES	17:15	
			06JAN2011	YES	8:50	YES	17:15	
			07JAN2011	YES	8:45	YES	17:35	
			08JAN2011	YES	8:55	YES	17:40	
			09JAN2011	YES	9:05	YES	17:35	
			10JAN2011	YES	9:05	YES	17:15	
			11JAN2011	YES	8:20	YES	21:50	
			12JAN2011	YES	8:55	YES	17:15	
			13JAN2011	YES	8:55	YES	17:15	
			14JAN2011	YES	9:10	YES	18:00	
			15JAN2011	YES	8:55	YES	17:25	
			16JAN2011	YES	9:15	YES	17:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	17JAN2011	YES	8:50	YES	17:25	
			18JAN2011	YES	8:20	YES	17:15	
			19JAN2011	YES	8:40	YES	17:25	
			20JAN2011	YES	8:45	YES	17:55	
			21JAN2011	YES	8:45	YES	17:20	
			22JAN2011	YES	8:50	YES	17:25	
			23JAN2011	YES	8:50	YES	17:30	
			24JAN2011	YES	8:45	YES	17:15	
			25JAN2011	YES	8:35	YES	17:45	
			26JAN2011	YES	8:40	YES	19:25	
			27JAN2011	YES	8:45	YES	17:10	
			28JAN2011	YES	8:45	YES	17:10	
			29JAN2011	YES	8:40	YES	18:05	
			30JAN2011	YES	9:05	YES	18:45	
			31JAN2011	YES	8:50	YES	17:15	
			01FEB2011	YES	8:40	YES	21:45	
			02FEB2011	YES	9:00	YES	17:15	
			03FEB2011	YES	8:35	YES	17:00	
			04FEB2011	YES	8:35	YES	16:55	
			05FEB2011	YES	9:10	YES	17:30	
			06FEB2011	YES	8:50	YES	17:10	
			07FEB2011	YES	7:50	YES	17:15	
			08FEB2011	YES	8:35	YES	17:20	
			09FEB2011	YES	8:50	YES	17:35	
			10FEB2011	YES	8:50	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	11FEB2011	YES	8:45	YES	17:10	
			12FEB2011	YES	8:40	YES	17:15	
			13FEB2011	YES	8:55	YES	18:50	
			14FEB2011	YES	8:35	YES	17:15	
			15FEB2011	YES	8:45	YES	17:10	
			16FEB2011	YES	8:40	YES	17:35	
			17FEB2011	YES	8:45	YES	17:20	
			18FEB2011	YES	8:40	YES	17:25	
			19FEB2011	YES	8:35	YES	17:15	
			20FEB2011	YES	8:55	YES	17:15	
			21FEB2011	YES	8:35	YES	17:25	
			22FEB2011	YES	8:15	YES	17:15	
			23FEB2011	YES	8:55	YES	17:40	
			24FEB2011	YES	8:50	YES	17:15	
			25FEB2011	YES	8:50	YES	17:20	
			26FEB2011	YES	8:50	YES	17:20	
			27FEB2011	YES	9:05	YES	17:40	
			28FEB2011	YES	8:50	YES	17:30	
			01MAR2011	YES	8:20	YES	17:10	
			02MAR2011	YES	8:50	YES	17:10	
			03MAR2011	YES	8:40	YES	17:10	
			04MAR2011	YES	8:45	YES	17:15	
			05MAR2011	YES	8:45	YES	17:10	
			06MAR2011	YES	8:40	YES	17:20	
			07MAR2011	YES	8:45	YES	20:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	030	8	08MAR2011	YES	8:50	YES	17:10	
			09MAR2011	YES	8:45	YES	17:15	
			10MAR2011	YES	8:35	YES	17:15	
			11MAR2011	YES	8:00	YES	17:20	
			12MAR2011	YES	8:45	YES	17:15	
			13MAR2011	YES	8:50	YES	17:15	
			14MAR2011	YES	7:45			
	032	8	18NOV2010	YES	13:10	YES	18:15	d. Frau Probst
			19NOV2010	YES	7:23	YES	18:19	
			20NOV2010	YES	7:30	YES	17:55	
			21NOV2010	YES	7:40	YES	17:35	
			22NOV2010	YES	7:30	YES	19:37	
			23NOV2010	YES	7:25	YES	18:45	
			24NOV2010	YES	7:30	YES	18:05	
			25NOV2010	YES	7:25	YES	19:45	
			26NOV2010	YES	7:40		18:30	
			27NOV2010	YES	7:20	YES	20:15	
			28NOV2010	YES	7:40	YES	19:00	
			29NOV2010	YES	7:15	YES	19:00	
			30NOV2010	YES	7:22	YES	18:50	
			01DEC2010	YES	7:15	YES	18:50	
			02DEC2010	YES	7:20	YES	19:00	
			03DEC2010	YES	7:30	YES	19:10	
			04DEC2010	YES	7:40		19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	032	8	05DEC2010	YES	7:30	YES	18:50	
			06DEC2010	YES	7:15	YES	18:40	
			07DEC2010	YES	7:20		20:10	
			08DEC2010	YES	7:30		19:10	
			09DEC2010	YES	7:30	YES	19:00	
			10DEC2010	YES	7:30	YES	19:00	
			11DEC2010	YES	7:40		18:50	
			12DEC2010	YES	7:20		19:00	
			13DEC2010	YES	7:30	YES	19:10	
			14DEC2010	YES	7:15	YES	18:45	
			15DEC2010	YES	7:10	YES	19:00	
			16DEC2010	YES	7:15	YES	19:10	
			17DEC2010	YES	7:20			
			18DEC2010	YES	7:25	YES	19:20	
			19DEC2010	YES	7:50	YES	19:20	
			20DEC2010	YES	7:20	YES	19:15	
			21DEC2010	YES	7:30	YES	18:50	
			22DEC2010	YES	7:20	YES	19:40	
			23DEC2010	YES	7:30	YES	19:20	
			24DEC2010	YES	7:15	YES	18:20	
			25DEC2010	YES	8:00	YES	18:50	
			26DEC2010	YES	7:30	YES	19:00	
			27DEC2010	YES	7:35	YES	19:20	
			28DEC2010	YES	7:20	YES	19:20	
			29DEC2010	YES	7:40	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	032	8	30DEC2010	YES	7:10	YES	18:50	
			31DEC2010	YES	7:20	YES	19:10	
			01JAN2011	YES	9:10	YES	18:50	
			02JAN2011	YES	7:30	YES	18:40	
			03JAN2011	YES	7:50	YES	19:00	
			04JAN2011	YES	7:20	YES	19:20	
			05JAN2011	YES	7:15	YES	19:00	
			06JAN2011	YES	7:40	YES	18:50	
			07JAN2011	YES	7:20	YES	19:00	
			08JAN2011	YES	7:20	YES	19:15	
			09JAN2011	YES	7:30	YES	20:00	
			10JAN2011	YES	7:10	YES	19:40	
			11JAN2011	YES	7:15	YES	18:40	
			12JAN2011	YES	7:25	YES	19:10	
			13JAN2011	YES	7:20	YES	18:50	
			14JAN2011	YES	7:10	YES	19:15	
			15JAN2011	YES	7:15	YES	19:25	
			16JAN2011	YES	8:00	YES	19:10	
			17JAN2011	YES	7:20	YES	20:40	
			18JAN2011	YES	7:30	YES	19:40	
			19JAN2011	YES	7:30	YES	19:10	
			20JAN2011	YES	7:30	YES	19:20	
			21JAN2011	YES	7:30	YES	19:00	
			22JAN2011	YES	7:20	YES	18:30	
			23JAN2011	YES	7:40	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	032	8	24JAN2011	YES	7:20	YES	19:30	
			25JAN2011	YES	8:00	YES	19:10	
			26JAN2011	YES	7:10	YES		
			27JAN2011	YES	7:50	YES	19:30	
			28JAN2011	YES	7:20	YES	19:10	
			29JAN2011	YES	7:20	YES	19:00	
			30JAN2011	YES	8:00	YES	19:10	
			31JAN2011	YES	7:40	YES	19:00	
			01FEB2011	YES	7:15	YES	19:20	
			02FEB2011	YES	7:10	YES	19:00	
			03FEB2011	YES	7:20	YES	19:30	
			04FEB2011	YES	7:20	YES	19:50	
			05FEB2011	YES	7:40	YES		
			06FEB2011	YES	7:40	YES	19:55	
			07FEB2011	YES	7:00			
	033	9	21DEC1996	YES	8:00	YES	18:30	
			20NOV2000	YES	7:30			
			04NOV2009			YES	18:30	
			05NOV2009	YES	7:40	YES	18:30	
			06NOV2009	YES	7:30	YES	17:50	
			07NOV2009	YES	8:00	YES	17:30	
			08NOV2009	YES	8:00	YES	17:45	
			09NOV2009	YES	7:30	YES	18:30	
			10NOV2009	YES	7:00		18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	11NOV2009	YES	7:30	YES	18:30	
			12NOV2009	YES	8:30	YES	18:30	
			13NOV2009	YES	7:30	YES	18:30	
			14NOV2009	YES	7:30	YES	18:00	
			15NOV2009	YES	7:30	YES	18:00	
			16NOV2009	YES	7:30	YES	18:30	
			17NOV2009	YES	7:30	YES	18:30	
			18NOV2009	YES	7:30	YES	18:30	
			19NOV2009	YES	7:30	YES	18:30	
			20NOV2009	YES	7:30	YES	18:30	
			21NOV2009	YES	8:00		18:00	
			22NOV2009	YES	7:00	YES	18:00	
			23NOV2009	YES	7:30	YES	18:30	
			24NOV2009	YES	7:30	YES	18:30	
			25NOV2009	YES	7:30	YES	18:30	
			26NOV2009	YES	7:30	YES	18:30	
			27NOV2009	YES	7:30	YES	19:00	
			28NOV2009	YES	7:30	YES	18:00	
			29NOV2009	YES	7:30	YES	18:00	
			30NOV2009	YES	7:30		18:30	
			01DEC2009	YES	8:00	YES	18:30	
			02DEC2009	YES	7:00			
			02DEC2009			YES	18:30	
			03DEC2009	YES	7:30	YES	18:30	
			04DEC2009	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	05DEC2009	YES	8:00	YES	18:30	
			06DEC2009	YES	7:30	YES	17:45	
			07DEC2009	YES	7:30	YES	18:30	
			08DEC2009	YES	7:30	YES	18:30	
			09DEC2009	YES	7:30	YES	18:30	
			10DEC2009	YES	7:30	YES	18:30	
			11DEC2009	YES	7:30	YES	18:30	
			12DEC2009	YES	7:30	YES	17:45	
			13DEC2009	YES	7:45	YES	17:30	
			14DEC2009	YES	8:15	YES	18:30	
			15DEC2009	YES	7:30	YES	18:30	
			16DEC2009	YES	7:30	YES	18:30	
			17DEC2009	YES	7:30	YES	23:30	
			18DEC2009	YES	7:30	YES	18:30	
			19DEC2009	YES	7:30		19:00	
			20DEC2009	YES	8:00	YES	22:30	
			22DEC2009	YES	8:00	YES	18:30	
			23DEC2009	YES	8:00	YES	18:30	
			24DEC2009	YES	8:00	YES	18:00	
			25DEC2009	YES	8:00	YES	18:00	
			26DEC2009	YES	9:00	YES	19:00	
			27DEC2009	YES	9:00	YES	18:00	
			28DEC2009	YES	9:00	YES	18:30	
			29DEC2009	YES	8:30	YES	18:30	
			30DEC2009	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	31DEC2009	YES	8:30	YES	19:30	
			01JAN2010		9:30	YES	18:30	
			02JAN2010		8:30	YES	18:30	
			03JAN2010	YES	7:30	YES	18:30	
			04JAN2010	YES	8:00	YES	18:30	
			05JAN2010	YES	8:00	YES	18:30	
			06JAN2010	YES	8:00	YES	19:00	
			07JAN2010	YES	8:00	YES	18:30	
			08JAN2010	YES	8:00	YES	18:30	
			09JAN2010	YES	8:30	YES	19:00	
			10JAN2010	YES	8:30	YES	18:00	
			11JAN2010	YES	8:00	YES	18:30	
			12JAN2010	YES	8:00	YES	18:30	
			13JAN2010	YES	8:30	YES	18:30	
			14JAN2010	YES	7:30	YES	18:30	
			15JAN2010	YES	8:00	YES	18:30	
			16JAN2010	YES	9:00	YES	19:00	
			17JAN2010	YES	9:00	YES	18:00	
			18JAN2010	YES	7:30	YES	18:30	
			19JAN2010	YES	8:00	YES	18:30	
			20JAN2010			YES	18:30	
			21JAN2010	YES	7:30	YES	18:30	
			22JAN2010	YES	8:00	YES	18:30	
			23JAN2010	YES	8:00	YES	19:00	
			24JAN2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	25JAN2010	YES	7:30	YES	18:30	
			26JAN2010	YES	7:30			
			26JAN2010			YES	22:30	Beginn mit Tabletten Visite 3
			27JAN2010	YES	7:30	YES	18:30	
			28JAN2010	YES	7:30	YES	18:30	
			29JAN2010	YES	7:30	YES	18:30	
			30JAN2010	YES	8:00	YES	18:30	
			31JAN2010	YES	8:00	YES	18:00	
			01FEB2010	YES	8:00	YES	18:30	
			02FEB2010	YES	8:30	YES	18:30	
			03FEB2010	YES	8:00	YES	18:30	
			04FEB2010	YES	7:30	YES	18:30	
			05FEB2010	YES	8:00	YES	17:00	
			06FEB2010	YES	8:00	YES	18:00	
			07FEB2010	YES	8:30	YES	18:00	
			08FEB2010	YES	8:00	YES	18:30	
			09FEB2010	YES	8:00	YES	18:30	
			10FEB2010	YES	8:00	YES	18:30	
			11FEB2010	YES	8:00	YES	18:30	
			12FEB2010	YES	8:00	YES	18:30	
			13FEB2010	YES	8:30	YES	19:00	
			14FEB2010	YES	8:30	YES	19:00	
			15FEB2010	YES	8:00	YES	18:30	
			16FEB2010	YES	8:00	YES	18:30	
			17FEB2010	YES	8:00	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	18FEB2010	YES	8:00	YES	18:30	
			19FEB2010	YES	8:00	YES	18:30	
			20FEB2010	YES	8:00	YES	18:00	
			21FEB2010	YES	8:00	YES	18:30	
			22FEB2010	YES	7:30	YES	18:30	
			23FEB2010	YES	8:00	YES	18:30	
			24FEB2010	YES	7:30	YES	18:30	
			25FEB2010	YES	7:30	YES	18:30	
			26FEB2010	YES	7:00	YES	18:30	
			27FEB2010	YES	8:30	YES	18:00	
			28FEB2010	YES	8:30	YES	18:00	
			01MAR2010	YES	8:00	YES	18:30	
			02MAR2010	YES	8:00	YES	18:30	
			03MAR2010	YES	8:00	YES	18:30	
			04MAR2010	YES	7:30	YES	18:30	
			05MAR2010	YES	8:00	YES	22:00	
			06MAR2010	YES	8:30	YES	23:30	
			07MAR2010	YES	9:00	YES	18:00	
			08MAR2010	YES	8:00	YES	18:30	
			09MAR2010	YES	7:30	YES	18:30	
			10MAR2010	YES	8:00	YES	18:30	
			11MAR2010	YES	7:30	YES	18:30	
			12MAR2010	YES	8:00	YES	18:30	
			13MAR2010	YES	8:00	YES	18:30	
			14MAR2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	15MAR2010	YES	8:00	YES	18:30	
			16MAR2010	YES	8:00	YES	18:30	
			17MAR2010	YES	8:00	YES	18:30	
			18MAR2010	YES	9:00	YES	20:30	18.03.-29.03. Urlaub
			19MAR2010	YES	7:00	YES	20:00	
			20MAR2010	YES	7:00	YES	20:00	
			21MAR2010	YES	7:30	YES	19:00	
			22MAR2010	YES	7:30	YES	19:00	
			22MAR2010	YES	7:30	YES	19:00	
			23MAR2010	YES	7:30	YES	19:00	
			24MAR2010	YES	7:30	YES	19:00	
			25MAR2010	YES	7:30	YES	19:00	
			26MAR2010	YES	8:00	YES	19:00	
			27MAR2010	YES	7:00	YES	20:00	
			28MAR2010	YES	7:00	YES	20:00	Zeitumstellung
			29MAR2010	YES	7:00	YES	20:00	
			30MAR2010	YES	9:00	YES	18:30	
			31MAR2010	YES	7:30	YES	18:30	
			01APR2010	YES	7:30	YES	18:30	
			02APR2010	YES	7:30	YES	18:30	
			03APR2010	YES	7:30	YES	18:30	
			04APR2010	YES	7:30	YES	19:00	
			05APR2010	YES	7:30	YES	19:00	
			06APR2010	YES	7:30	YES	18:30	
			07APR2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	08APR2010	YES	7:30	YES	18:30	
			09APR2010	YES	8:00	YES	18:30	
			10APR2010	YES	8:00	YES	18:00	
			11APR2010	YES	7:30	YES	18:00	
			12APR2010	YES	8:00	YES	18:30	
			13APR2010	YES	8:00	YES	18:30	
			14APR2010	YES	8:00	YES	18:30	
			15APR2010	YES	8:00	YES	18:30	
			16APR2010	YES	8:00	YES	18:30	
			17APR2010	YES	8:00	YES	18:00	
			18APR2010	YES	8:00	YES	18:00	
			19APR2010	YES	8:00	YES	18:30	
			20APR2010	YES	8:00	YES	18:30	
			21APR2010	YES	7:00			
			21APR2010			YES	18:30	
			22APR2010	YES	7:30	YES	18:30	
			23APR2010	YES	8:00	YES	18:00	
			24APR2010	YES	8:00	YES	18:30	
			25APR2010	YES	7:30	YES	18:00	
			26APR2010	YES	7:30	YES	18:30	
			27APR2010	YES	7:00	YES	18:30	
			28APR2010	YES	7:30	YES	18:30	
			29APR2010	YES	7:00	YES	18:30	
			30APR2010	YES	8:00	YES	18:30	
			01MAY2010	YES	8:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	02MAY2010	YES	8:00	YES	18:00	
			03MAY2010	YES	8:00	YES	18:30	
			04MAY2010	YES	7:30	YES	18:30	
			05MAY2010	YES	7:30	YES	18:30	
			06MAY2010	YES	7:30	YES	18:30	
			07MAY2010	YES	7:30	YES	18:30	
			08MAY2010	YES	7:30	YES	19:00	
			09MAY2010	YES	8:00	YES	18:00	
			10MAY2010	YES	8:00	YES	18:30	
			11MAY2010	YES	8:00	YES	18:30	
			12MAY2010	YES	8:00	YES	18:30	
			13MAY2010	YES	8:00	YES	18:30	
			14MAY2010	YES	8:00	YES	19:00	
			15MAY2010	YES	8:00	YES	19:30	
			16MAY2010	YES	8:00	YES	18:00	
			17MAY2010	YES	8:00	YES	18:30	
			18MAY2010	YES	9:00	YES	18:30	
			19MAY2010	YES	7:30	YES	18:30	
			20MAY2010	YES	7:00	YES	18:30	
			21MAY2010	YES	7:30	YES	18:30	
			22MAY2010	YES	7:30	YES	20:30	
			23MAY2010	YES	9:00	YES	18:00	
			24MAY2010	YES	8:00	YES	19:00	
			25MAY2010	YES	8:00	YES	18:30	
			26MAY2010	YES	8:00	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	27MAY2010	YES	7:00	YES	18:30	
			28MAY2010	YES	7:30	YES	18:30	
			29MAY2010	YES	9:00	YES	18:00	Müdigkeit_ verändertes Schlafverh.
			30MAY2010	YES	9:00	YES	18:00	
			31MAY2010	YES	9:30	YES	18:30	
			01JUN2010	YES	8:30	YES	22:30	
			02JUN2010	YES	9:00	YES	18:30	
			03JUN2010	YES	9:00	YES	18:30	
			04JUN2010	YES	11:30	YES	21:00	Bis Mittag geschlafen
			05JUN2010	YES	7:30	YES	18:00	
			06JUN2010	YES	7:30	YES	18:00	
			07JUN2010	YES	7:30	YES	18:30	Blutentnahme Hausarzt_ Zeckenschutzimpfung
			08JUN2010	YES	7:30	YES	18:30	
			09JUN2010	YES	8:00	YES	19:30	
			10JUN2010	YES	8:00	YES	18:30	
			11JUN2010	YES	7:30	YES	18:30	
			12JUN2010	YES	7:30	YES	19:00	
			13JUN2010	YES	8:00	YES	20:00	
			14JUN2010	YES	8:30	YES	18:30	
			15JUN2010	YES	8:00	YES	18:30	
			16JUN2010	YES	8:00	YES	18:30	
			17JUN2010	YES	7:30	YES	18:30	
			18JUN2010	YES	7:30	YES	18:30	
			19JUN2010	YES	8:00	YES	19:00	
			20JUN2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	21JUN2010	YES	7:30	YES	18:30	
			22JUN2010	YES	7:30	YES	18:30	
			23JUN2010	YES	7:30	YES	18:30	
			24JUN2010	YES	7:30	YES	18:30	
			25JUN2010	YES	7:30	YES	18:30	
			26JUN2010	YES	7:30	YES	22:15	
			27JUN2010	YES	7:30	YES	20:00	
			28JUN2010	YES	7:30	YES	18:30	
			29JUN2010	YES	7:30	YES	18:30	
			30JUN2010	YES	7:30	YES	18:30	
			01JUL2010	YES	7:30	YES	18:30	
			02JUL2010	YES	8:00	YES	18:30	
			03JUL2010	YES	8:00	YES	18:30	
			04JUL2010	YES	8:00	YES	19:00	
			05JUL2010	YES	8:00	YES	18:30	
			06JUL2010	YES	8:00	YES	18:30	
			07JUL2010	YES	8:00	YES	18:30	
			08JUL2010	YES	8:00	YES	18:30	
			09JUL2010	YES	8:00	YES	18:30	
			10JUL2010	YES	8:00	YES	18:00	
			11JUL2010	YES	8:00	YES	19:00	
			12JUL2010	YES	8:00	YES	18:00	
			13JUL2010	YES	8:00	YES	18:00	
			14JUL2010	YES	8:00	YES	18:00	
			15JUL2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	16JUL2010	YES	8:00	YES	18:00	
			17JUL2010	YES	8:00	YES	18:00	
			18JUL2010	YES	11:00	YES	18:00	
			19JUL2010	YES	8:30	YES	18:30	
			20JUL2010	YES	8:30	YES	18:30	
			21JUL2010	YES	8:00	YES	18:30	
			22JUL2010	YES	7:30			
			22JUL2010			YES	18:30	
			23JUL2010	YES	8:00	YES	18:30	
			24JUL2010	YES	8:00	YES	19:00	
			25JUL2010	YES	8:00	YES	18:00	
			26JUL2010	YES	8:00	YES	18:30	
			27JUL2010	YES	8:00	YES	18:30	
			28JUL2010	YES	8:00	YES	18:30	
			29JUL2010	YES	8:00	YES	18:30	
			30JUL2010	YES	8:00	YES	18:30	
			31JUL2010	YES	8:30	YES	18:00	
			01AUG2010	YES	8:30	YES	18:00	
			02AUG2010	YES	8:30	YES	18:30	
			03AUG2010	YES	8:30	YES	18:30	
			04AUG2010	YES	8:00	YES	22:00	
			05AUG2010	YES	8:30	YES	18:30	
			06AUG2010	YES	8:30	YES	18:30	
			07AUG2010	YES	8:30	YES	20:30	
			08AUG2010	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	09AUG2010	YES	8:30	YES	18:30	
			10AUG2010	YES	7:30	YES	18:30	
			11AUG2010	YES	7:30	YES	18:30	
			12AUG2010	YES	7:30	YES	18:30	
			13AUG2010	YES	7:30	YES	18:30	
			14AUG2010	YES	7:30	YES	19:00	
			15AUG2010	YES	7:30	YES	18:00	
			16AUG2010	YES	7:30	YES	18:30	
			17AUG2010	YES	7:30	YES	18:30	
			18AUG2010	YES	8:30	YES	18:30	
			19AUG2010	YES	8:30	YES	18:30	
			20AUG2010	YES	8:30	YES	18:30	
			21AUG2010	YES	8:00	YES	19:00	
			22AUG2010	YES	8:00	YES	20:00	
			23AUG2010	YES	8:30	YES	19:00	
			24AUG2010	YES	7:30	YES	18:30	
			25AUG2010	YES	7:30	YES	18:30	
			26AUG2010	YES	7:30	YES	18:30	
			27AUG2010	YES	8:00	YES	18:30	
			28AUG2010	YES	7:30	YES	18:30	
			29AUG2010	YES	8:00	YES	18:30	
			30AUG2010	YES	8:00	YES	18:30	
			31AUG2010	YES	8:00	YES	18:30	
			01SEP2010	YES	8:00	YES	18:30	
			02SEP2010	YES	8:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	03SEP2010	YES	8:00	YES	22:00	
			04SEP2010	YES	8:00	YES	18:30	
			05SEP2010	YES	7:30	YES	19:00	
			06SEP2010	YES	7:30	YES	18:30	
			07SEP2010	YES	7:30	YES	18:30	
			08SEP2010	YES	7:30	YES	18:30	
			09SEP2010	YES	7:30	YES	18:30	
			10SEP2010	YES	7:30	YES	20:30	
			11SEP2010	YES	9:00	YES	18:30	
			12SEP2010	YES	8:30	YES	18:00	
			13SEP2010	YES	8:30	YES	18:30	
			14SEP2010	YES	8:30	YES	18:30	
			15SEP2010	YES	8:00	YES	18:30	
			16SEP2010	YES	8:00	YES	18:30	
			17SEP2010	YES	8:00	YES	18:30	
			18SEP2010	YES	8:00	YES	20:00	
			19SEP2010	YES	7:30	YES	18:00	
			20SEP2010	YES	7:30	YES	18:30	
			21SEP2010	YES	7:30	YES	18:30	
			22SEP2010	YES	7:30	YES	18:30	
			23SEP2010	YES	7:30	YES	18:30	
			24SEP2010	YES	7:30	YES	18:30	
			25SEP2010	YES	7:30	YES	18:00	
			26SEP2010	YES	7:30	YES	18:00	
			27SEP2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	28SEP2010	YES	7:30	YES	18:30	
			29SEP2010	YES	7:30	YES	18:30	
			30SEP2010	YES	7:30	YES	18:30	
			01OCT2010	YES	7:30	YES	18:30	
			02OCT2010	YES	7:30	YES	18:00	
			03OCT2010	YES	7:30	YES	18:00	
			04OCT2010	YES	7:30	YES	18:30	
			05OCT2010	YES	7:30	YES	18:30	
			06OCT2010	YES	7:30	YES	18:30	
			07OCT2010	YES	7:30	YES	18:30	
			08OCT2010	YES	7:30	YES	18:30	
			09OCT2010	YES	9:00	YES	18:00	
			10OCT2010	YES	8:30	YES	18:00	
			11OCT2010	YES	7:30	YES	18:30	
			12OCT2010	YES	7:30	YES	18:30	
			13OCT2010	YES	7:30	YES	18:30	
			14OCT2010	YES	7:30	YES	18:30	
			15OCT2010	YES	7:30	YES	18:30	
			16OCT2010	YES	8:00	YES	20:30	
			17OCT2010	YES	8:00	YES	19:00	
			18OCT2010	YES	8:00	YES	18:30	
			19OCT2010	YES	8:00	YES	18:30	
			20OCT2010	YES	9:00	YES	18:30	
			21OCT2010	YES	8:00	YES	18:30	
			22OCT2010	YES	8:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	033	9	23OCT2010	YES	8:00	YES	18:30	
			24OCT2010	YES	8:00	YES	18:00	
			25OCT2010	YES	8:00	YES	18:30	
			26OCT2010	YES	8:00	YES	18:30	
			27OCT2010	YES	8:00	YES	18:30	
			28OCT2010	YES	8:00	YES	18:30	
			29OCT2010	YES	8:30	YES	18:30	
			30OCT2010	YES	8:00	YES	22:30	
			31OCT2010	YES	8:00	YES	22:30	
			01NOV2010	YES	8:00	YES	18:30	
			02NOV2010	YES	8:00	YES	18:30	
			03NOV2010	YES	8:00	YES	18:30	
			04NOV2010	YES	8:00	YES	18:30	
			05NOV2010	YES	8:00	YES	18:30	
			06NOV2010	YES	8:00	YES	18:00	
			07NOV2010	YES	8:00	YES	18:30	
			08NOV2010	YES	8:00	YES	18:30	
			09NOV2010	YES	12:30	YES	18:30	
			10NOV2010	YES	6:30			
	042	12				YES	17:30	
						YES	17:30	
						YES	17:30	
						YES	17:45	
						YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12				YES	17:30	
			14JAN2010			YES	17:30	
			15JAN2010	YES	8:15			
			16JAN2010	YES	9:45			
			17JAN2010	YES	8:00			
			18JAN2010	YES	7:30			
			19JAN2010	YES	7:45	YES	17:30	
			20JAN2010	YES	8:00			
			21JAN2010	YES	7:45			
			22JAN2010	YES	7:30	YES	17:30	
			23JAN2010	YES	7:45	YES	17:45	
			24JAN2010	YES	8:00	YES	18:10	
			25JAN2010	YES	7:15	YES	17:30	
			26JAN2010	YES	7:45	YES	17:35	
			27JAN2010	YES	8:00	YES	17:40	
			28JAN2010	YES	7:50	YES	17:55	
			29JAN2010	YES	7:30	YES	17:30	
			30JAN2010	YES	7:35	YES	17:40	
			31JAN2010	YES	7:50	YES	17:30	
			01FEB2010	YES	7:40	YES	17:50	
			02FEB2010	YES	7:35	YES	17:45	
			03FEB2010	YES	7:15	YES	17:30	
			04FEB2010	YES	7:40	YES	17:30	
			05FEB2010	YES	7:00	YES	17:40	
			06FEB2010	YES	7:15	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	07FEB2010	YES	7:30	YES	17:30	
			08FEB2010	YES	7:00	YES	17:40	
			09FEB2010	YES	7:10	YES	17:30	
			10FEB2010	YES	7:20	YES	17:45	
			11FEB2010	YES	7:30			
			11FEB2010			YES	17:45	
			12FEB2010	YES	7:15	YES	18:00	
			13FEB2010	YES	7:10	YES	17:50	
			14FEB2010	YES	7:00	YES	17:45	
			15FEB2010	YES	7:15	YES	18:10	
			16FEB2010	YES	7:00	YES	18:05	
			17FEB2010	YES	7:10	YES	18:10	
			18FEB2010	YES	7:00	YES	18:15	
			19FEB2010	YES	7:10	YES	18:10	
			20FEB2010	YES	6:45	YES	18:15	
			21FEB2010	YES	7:00	YES	18:10	
			22FEB2010	YES	7:00	YES	18:00	
			23FEB2010	YES	6:50	YES	17:45	
			24FEB2010	YES	7:10	YES	18:15	
			25FEB2010	YES	7:30	YES	18:30	
			26FEB2010	YES	7:10	YES	17:50	
			27FEB2010	YES	7:15	YES	18:10	
			28FEB2010	YES	7:20	YES	18:15	
			01MAR2010	YES	7:15	YES	18:30	
			02MAR2010	YES	6:45	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	03MAR2010	YES	6:50	YES	17:50	
			04MAR2010	YES	7:00	YES	18:05	
			05MAR2010	YES	7:15	YES	18:10	
			06MAR2010	YES	7:20	YES	18:15	
			07MAR2010	YES	6:50	YES	17:50	
			25MAR2010	NO		YES	18:30	Ist örtlich u. zeitlich desorientiert, hat Kontakt z. Mitbewohner.
			26MAR2010	YES	8:30	YES	18:30	War um 05:30 schon angezogen, wollte einkaufen ist freundlich.
			27MAR2010	YES	8:30	YES	18:30	War um 05:30 Uhr im Haupteingang, wollte ihren Mann besuchen.
			28MAR2010	YES	8:30	YES	18:30	Ist örtlich u. zeitlich und situativ desorientiert, aber gut gelaunt.
			29MAR2010	YES	8:30	YES	18:30	Schlecht geschlafen, 05:30 wollte einkaufen.
			30MAR2010	YES	8:30	YES	18:30	Hat gut geschlafen bis 06:30, ist positiv u. freundlich.
			31MAR2010	YES	8:30	YES	18:30	Schlecht geschlafen, um 05:30 war i. Parkplatz. Bew. sehr unruhig.
			01APR2010	YES	8:30	YES	18:30	Bew. im Zimmer im Bett, aber nicht geschlafen. Bew. war um 06:00 schon angezogen.
			02APR2010	YES	8:30	YES	18:30	Bew. ganze Nacht nicht geschlafen. Hat geweint weil Ihr Mann operiert ist. Bew. ist ruhig u. freundlich, aber sucht Ihren Mann.

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	03APR2010	YES	8:30	YES	18:30	Bew. nicht geschlafen, Bew. war um 06:00 schon angezogen_ geht oft in fremde Zimmer. Bew. ruhig, sucht immer ihr Zimmer.
			04APR2010	YES	8:30	YES	18:30	Bew. ganze Nacht nicht geschlafen. Bew. ist ruhig.
			05APR2010	YES	7:30	YES	16:30	Bew. hat ganze Nacht geschlafen. Bew. wird im Laufe des Tages zunehmend ruheloser, ist aber immer freundlich. Pat. ist leicht erkältet.
			06APR2010	YES	7:30	YES	16:30	Bew. lag im Bett und schläft. Erkältet.
			07APR2010	YES	7:30	YES	16:30	Bew. hat nicht geschlafen. War um 06:30 schon angezogen. Bew. sucht ständig ihr Zimmer.
			08APR2010	YES	7:30	YES	16:30	23:00 - nicht geschlafen. 03:00 - schläft. Desorientiert-freundlich.
			09APR2010	YES	7:30	YES	16:30	Hat geschlafen.
			10APR2010	YES	7:30	YES	16:30	Hat geschlafen. War schon um 06:30 angezogen. Hat ihren Mann gesucht.
			11APR2010	YES	7:30	YES	16:30	War schon angezogen. Bew. geht ständig in fremde Zimmer. Schläft.
			12APR2010	YES	7:30	YES	16:30	Hat nicht geschl. um 23:00. Ruhig - desorientiert zeitlich, örtlich u. situativ.
			13APR2010	YES	7:30	YES	16:30	Hat geschlafen. Feundlich - desorientiert.
			14APR2010	YES	7:30	YES	16:30	Unverändert. Sehr unruhig, sucht ihr Zimmer ständig.
			15APR2010	YES	7:30	YES	16:30	Bew. hat geschlafen. Gut gelaunt.
			16APR2010	YES	7:30	YES	16:30	Bew. schläft in der Nacht. Zeitlich, örtlich u. situativ desorientiert.

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	17APR2010	YES	7:30	YES	16:30	Bew. geschlafen. Ruhig u. freundlich.
			18APR2010	YES	7:30	YES	16:30	In der Nacht ruhig, schläft. Ruhig, desorientiert.
			19APR2010	YES	7:30	YES	16:30	Bis 03:00 geschlafen. Unverändert. Ruhig u. freundlich.
			20APR2010	YES	7:30	YES	16:30	Bew. geschlafen. Ruhig. Ruhig, hat aber ihr Zimmer oft gesucht.
			21APR2010	YES	7:30	YES	16:30	Bew. schläft in der Nacht.
			22APR2010	YES	7:30	YES	16:30	Bew. ruhig, hat geschlafen.
			23APR2010	YES	7:30	YES	16:30	o.b. Vorkommnisse
			24APR2010	YES	7:30	YES	16:30	Bew. ruhig, ist aber wach. Unverändert.
			25APR2010	YES	7:30	YES	16:30	Bew. ruhig, ist aber wach. Ruhig.
			26APR2010	YES	7:30	YES	16:30	Orientiert nur z. Person.
			27APR2010	YES	7:30	YES	16:30	Freundlich.
			28APR2010	YES	7:30	YES	16:30	Bew. schläft. Bew. ist freundlich, findet aber ihr Zimmer nicht.
			29APR2010	YES	7:30	YES	16:30	In der Nacht ruhig. Bew. war freundlich um 07:00 wach. Bew. freundlich, hat abends immer Zimmer gesucht.
			30APR2010	YES	7:30	YES	17:00	Schläft. Freundlich.
			01MAY2010	YES	7:30	YES	17:00	Ruhig. Ruhig.
			02MAY2010	YES	7:30	YES	17:00	Bew. ruhig. Freundlich, ruhig. Sucht immer ihr Zimmer.
			03MAY2010	YES	7:30	YES	17:00	Bew. ist ab 03:00 Uhr angezogen und im Gang gegessen. Freundlich, ruhig.
			04MAY2010	YES	7:30	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	05MAY2010	YES	7:10	YES	17:45	Ehefrau wirkt nach der 2 monatigen Trennung noch abwesender als sonst. Befolgt kaum noch kleine Anweisungen. Ehefrau wirkt nach der 2 monatigen Trennung noch abwesender als sonst. Befolgt kaum noch kleine Anweisungen.
			06MAY2010	YES	7:20			
			07MAY2010	YES	7:30	YES	17:15	
			08MAY2010	YES	7:00	YES	17:05	
			09MAY2010	YES	7:10	YES	17:15	
			10MAY2010	YES	7:05	YES	17:10	
			11MAY2010	YES	7:10	YES	17:35	
			12MAY2010	YES	7:05	YES	17:25	
			13MAY2010	YES	7:10	YES	17:05	
			14MAY2010	YES	7:15	YES	17:15	
			15MAY2010	YES	7:05	YES	17:30	
			16MAY2010	YES	6:45	YES	17:30	
			17MAY2010	YES	7:05	YES	17:15	
			18MAY2010	YES	7:10	YES	17:25	
			18MAY2010	YES		YES		
			19MAY2010	YES				
			19MAY2010	YES		YES		
			20MAY2010	YES	6:30	YES	17:20	
			21MAY2010	YES	6:40	YES	17:30	
			22MAY2010	YES	6:30	YES	17:15	Nachts um 03:00 Uhr aufgestanden.

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	23MAY2010	YES	6:45	YES	17:30	Pfingstsonntag um 03:00 Uhr aufgestanden, ich muß in die Schule - abends um 21:00 Uhr wollte sie zur Arbeitsstätte gefahren werden.
			24MAY2010	YES	6:15	YES	17:05	
			25MAY2010	YES	6:20	YES	17:10	
			26MAY2010	YES	6:25	YES	17:20	Weiterhin sehr unruhig und fahrig.
			27MAY2010	YES	6:45	YES	17:30	
			28MAY2010	YES	6:10	YES	17:15	
			29MAY2010	YES	6:40	YES	17:25	
			30MAY2010	YES	6:35	YES	17:30	
			31MAY2010	YES	6:45	YES	17:35	
			01JUN2010	YES	6:35	YES	17:20	
			02JUN2010	YES	6:20	YES	17:15	
			03JUN2010	YES	6:25	YES	17:20	
			04JUN2010	YES	6:30	YES	17:15	
			05JUN2010	YES	6:40	YES	17:35	
			06JUN2010	YES	7:05	YES	17:30	Wiederum Kaffeetisch für mehrere Personen gedeckt, ohne das Besuch kam.
			07JUN2010	YES	6:45	YES	17:15	
			08JUN2010	YES	6:15	YES	17:30	
			09JUN2010	YES	6:30	YES	17:30	
			10JUN2010	YES	6:40	YES	17:40	
			11JUN2010	YES	6:35	YES	17:50	
			12JUN2010	YES	6:30	YES	17:45	
			13JUN2010	YES	6:45	YES	17:40	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	14JUN2010	YES	6:45	YES	17:40	
			15JUN2010	YES	6:40	YES	17:50	
			16JUN2010	YES	6:30	YES	17:55	
			17JUN2010	YES	6:15	YES	18:30	
			17JUN2010	YES	6:45	YES	18:00	Wiederum nachmittags für Gäste Tisch gedeckt (ohne Gästebuch).
			18JUN2010	YES	6:50	YES	18:10	
			19JUN2010	YES	6:45	YES	18:20	
			20JUN2010	YES	6:55	YES	18:30	
			21JUN2010	YES	7:00	YES	18:45	
			22JUN2010	YES	6:30	YES	18:15	Ehefrau friert häufig, trägt bei höheren Temperaturen über 20° immer einen Wollpullover.
			23JUN2010	YES	7:10	YES	18:30	
			24JUN2010	YES	6:45	YES	18:10	
			25JUN2010	YES	6:50	YES	18:45	Sie hat Ehemann nach dessen Ehefrau gefragt!!!
			26JUN2010	YES	7:10	YES	18:35	
			27JUN2010	YES	7:00	YES	18:40	Sie sieht häufig kleine Kinder in der Wohnung.
			28JUN2010	YES	6:50	YES	18:15	
			29JUN2010	YES	6:45	YES	17:50	
			30JUN2010	YES	6:30			
			30JUN2010			YES	18:15	
			01JUL2010	YES	6:15	YES	18:10	
			02JUL2010	YES	6:20	YES	18:15	
			03JUL2010	YES	6:30	YES	18:40	
			04JUL2010	YES	6:40	YES	18:15	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	05JUL2010	YES	6:45	YES	17:00	Einweisung Seniorenresidenz Lindenpark -E- auf Station 5 aufgenommen
			06JUL2010	YES	8:00	YES	17:00	
			07JUL2010	YES	8:00	YES	17:00	
			08JUL2010	YES	8:00	YES	17:00	
			09JUL2010	YES	8:00	YES	18:30	
			10JUL2010	YES	8:00	YES	18:30	
			11JUL2010	YES	8:00	YES	18:30	
			12JUL2010	YES	8:00	YES	18:30	
			13JUL2010	YES	8:00	YES	18:30	
			14JUL2010	YES	8:00	YES	18:30	
			15JUL2010	YES	8:00	YES	18:30	
			16JUL2010	YES	8:00	YES	18:30	
			17JUL2010	YES	8:00	YES	18:30	
			18JUL2010	YES	8:00	YES	18:00	
			19JUL2010	YES	8:00	YES	18:00	
			20JUL2010	YES	8:00	YES	18:00	
			21JUL2010	YES	8:00	YES	18:00	
			22JUL2010	YES	8:00	YES	18:00	
			23JUL2010	YES	8:00	YES	18:00	
			24JUL2010	YES	8:00	YES	18:00	
			25JUL2010	YES	8:00	YES	18:00	
			26JUL2010	YES	8:00	YES	18:00	
			27JUL2010	YES	8:00	YES	18:00	
			28JUL2010	YES	8:00	YES	18:00	
			29JUL2010	YES	8:00	YES	18:00	

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	30JUL2010	YES	8:00	YES	18:00	
			31JUL2010	YES	8:00	YES		
			01AUG2010			YES	17:30	Einzug erst gegen 10:30 Uhr in der Pro Seniore Residenz Waldburg
			02AUG2010	YES	8:20	YES	17:40	
			03AUG2010	YES	8:00	YES	17:30	
			04AUG2010	YES	8:30	YES	17:40	
			05AUG2010	YES	8:00	YES	17:15	
			06AUG2010	YES	8:00	YES	17:00	
			07AUG2010	YES	8:00	YES	17:30	
			08AUG2010	YES	7:40	YES	17:30	
			09AUG2010	YES	7:45	YES	17:50	
			10AUG2010	YES	8:10	YES	17:40	
			11AUG2010	YES	7:35	YES	17:50	Bewohner heute orientierter
			12AUG2010	YES	7:35	YES	17:40	
			13AUG2010	YES	7:20	YES	17:50	
			14AUG2010	YES	7:15	YES	17:20	
			15AUG2010	YES	7:20	YES	17:50	
			16AUG2010	YES	7:10	YES	17:50	
			17AUG2010	YES	7:30	YES	17:25	
			18AUG2010	YES	8:15	YES	17:30	
			19AUG2010	YES	8:20	YES		
			20AUG2010	YES	8:00	YES	17:30	
			21AUG2010			YES	17:45	
			22AUG2010	YES	8:00	YES	17:30	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	23AUG2010	YES	7:40	YES	17:50	
			24AUG2010	YES	7:35	YES		
			25AUG2010	YES	7:28	YES		
			26AUG2010	YES	7:27	YES		
			27AUG2010			YES	17:25	
			28AUG2010	YES	7:45	YES	17:25	
			29AUG2010	YES	8:20	YES	17:25	
			30AUG2010	YES	8:50	YES	17:30	
			31AUG2010	YES	9:00	YES	17:30	
			01SEP2010	YES	8:10	YES	18:00	
			02SEP2010	YES	7:35	YES	18:00	
			02SEP2010	YES		YES		
			03SEP2010	YES	7:35	YES		
			03SEP2010	YES		YES		
			04SEP2010	YES	7:30	YES		
			04SEP2010			YES	17:30	
			05SEP2010	YES	8:00	YES	19:30	
			06SEP2010	YES	7:50	YES	17:50	
			07SEP2010	YES	7:10	YES	17:30	
			08SEP2010	YES	8:00	YES	17:30	
			09SEP2010	YES	8:00	YES	17:30	
			10SEP2010	YES	8:10	YES		
			11SEP2010	YES	8:15	YES	17:40	
			12SEP2010	YES	7:45	YES		Packungsende!
			22SEP2010			YES	17:50	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	23SEP2010	YES	8:00	YES	17:30	
			24SEP2010	YES	8:00	YES	17:30	
			25SEP2010	YES	8:00	YES	17:20	
			26SEP2010	YES	8:20	YES	17:40	
			27SEP2010			YES	17:30	
			28SEP2010	YES	8:20	YES	17:35	Morgens: starkes Abwehrverhalten
			29SEP2010	YES	8:00	YES	17:40	
			30SEP2010	YES	8:00	YES	17:30	
			01OCT2010	YES	7:45	YES	17:30	
			02OCT2010	YES	8:18	YES	17:35	Bew.gut lenkbar u. kooperativ heute.
			03OCT2010	YES	8:00	YES	17:40	dito
			04OCT2010		7:45	YES	17:50	
			05OCT2010		8:00	YES	17:50	
			06OCT2010	YES	8:20	YES	17:45	
			07OCT2010	YES	8:30	YES	17:45	
			08OCT2010	YES	8:00	YES	17:35	
			09OCT2010	YES	8:00	YES	17:40	
			10OCT2010			YES	18:00	
			11OCT2010	YES	8:20	YES	17:45	Morgens: leichte Aggressivität
			12OCT2010	YES	7:50		17:30	
			13OCT2010	YES	8:15		18:00	
			14OCT2010	YES	8:00		17:45	
			15OCT2010	YES	8:10		17:30	
			16OCT2010	YES	8:20	YES	17:50	
			17OCT2010	YES	8:10	YES	17:50	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	18OCT2010	NO	8:00	YES	17:50	
			19OCT2010	YES	7:45	YES	17:45	
			20OCT2010	YES	8:00	NO	18:00	abgelehnt
			21OCT2010	YES	8:15	NO	18:00	abgelehnt
			22OCT2010	YES	8:00	YES	18:00	
			23OCT2010	YES	8:05	YES	17:50	
			24OCT2010	YES	8:00	YES	18:10	
			25OCT2010	YES	8:00	YES	18:00	
			26OCT2010	YES	8:00	YES	17:45	
			27OCT2010	YES	8:00	YES	17:50	
			28OCT2010	NO	8:00	YES	18:10	
			29OCT2010	YES	8:15	YES	19:00	
			30OCT2010	YES	7:45	YES	17:45	
			31OCT2010	YES	8:00	YES	17:40	
			01NOV2010	YES	7:30	YES	17:50	
			02NOV2010	YES	7:45	YES	18:00	
			03NOV2010	YES	7:50	YES	18:00	
			04NOV2010	YES	8:00	YES	18:00	
			05NOV2010	YES	8:00	YES	18:00	
			06NOV2010	YES	8:00	YES	17:50	
			07NOV2010	YES	8:00	NO	18:00	abgelehnt
			08NOV2010	YES	8:00	YES	18:20	
			09NOV2010	YES	8:00	YES	18:00	
			10NOV2010	YES	8:00	YES	18:00	
			11NOV2010	YES	7:45	YES	17:50	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	12NOV2010	YES	7:40	YES	17:45	
			13NOV2010	YES	8:00	YES	17:30	
			14NOV2010	YES	8:00	YES	18:00	
			15NOV2010			NO	17:45	
			16NOV2010	YES	8:20	YES	17:40	
			17NOV2010	YES	8:00	YES	17:20	
			18NOV2010	YES	8:20	YES	17:30	
			19NOV2010	YES	8:00	YES	17:45	
			20NOV2010	YES	8:00	YES	17:30	
			21NOV2010	YES	7:50	YES	17:20	
			22NOV2010	YES	8:00	YES	17:40	
			23NOV2010	YES	7:50	YES	17:35	
			24NOV2010	YES		YES	17:50	
			25NOV2010	YES	8:00	YES	17:45	
			26NOV2010	YES	8:00	YES	17:30	
			27NOV2010	YES	8:00	YES	18:00	
			28NOV2010	YES	7:50	YES	18:00	
			29NOV2010	YES	7:50	YES	17:30	
			30NOV2010	YES	7:45	YES	18:00	
			01DEC2010	YES	8:15	YES		
			02DEC2010	YES	8:40	YES	17:50	
			03DEC2010	YES	7:50	YES	18:00	
			04DEC2010	YES	8:00	YES	18:00	
			05DEC2010	YES	8:20	YES	18:00	
			06DEC2010	YES	7:50	YES	18:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	07DEC2010	YES	7:45	YES	18:00	
			08DEC2010	YES	8:00	YES	17:00	
			09DEC2010	YES	8:00	YES	17:20	
			10DEC2010	YES	8:00	YES	17:50	
			11DEC2010	YES	8:00	YES	18:00	
			12DEC2010	YES	8:00	YES	18:20	
			13DEC2010	YES	8:20	YES	18:00	
			14DEC2010	YES	7:40	YES	18:15	
			15DEC2010	YES	8:20	YES	17:35	
			16DEC2010	YES	8:00	YES	17:50	
			17DEC2010	YES	8:00	YES	17:45	
			18DEC2010	YES	8:00	YES	17:55	
			19DEC2010	YES	8:00	YES	18:00	
			20DEC2010	YES	8:00	YES	18:00	
			21DEC2010	YES	8:00	YES	8:00	
			22DEC2010	YES	7:50	YES	18:20	
			23DEC2010	YES	8:10	YES	18:30	
			24DEC2010	YES	8:20	YES	17:50	
			25DEC2010	YES	8:00	YES	18:00	
			26DEC2010	YES	8:00	YES	17:45	
			27DEC2010	YES	8:31	YES	18:10	
			28DEC2010	YES	9:00	YES	17:35	
			29DEC2010	YES	8:10	YES	18:00	
			30DEC2010	YES	7:50	YES	18:00	
			31DEC2010	YES	8:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	042	12	01JAN2011	YES	8:00	YES	17:35	
			02JAN2011	YES	8:40	YES	18:00	
			03JAN2011	YES	8:15	YES	18:00	
			04JAN2011	YES	8:50	YES	17:50	
			05JAN2011	YES	8:00	YES	17:50	
			06JAN2011	YES	8:20	YES	18:10	
			07JAN2011	YES	8:00	YES	18:00	
			08JAN2011	YES	8:31	YES	18:00	
			09JAN2011	YES	9:00	YES	18:00	
			10JAN2011	YES	8:10	YES	17:59	
			11JAN2011	YES	8:00	YES	18:00	
	043	12	24NOV2008	YES	6:30	YES	18:08	
			19NOV2009	YES	8:00	YES	18:00	
			20NOV2009	YES	7:35	YES	18:05	
			21NOV2009	YES	6:00	YES	18:10	
			22NOV2009	YES	6:30	YES	18:05	
			23NOV2009	YES	6:30	YES	18:00	nachm. trockenen Mund
			25NOV2009	YES	6:50	YES	18:00	
			26NOV2009	YES	7:00	YES	18:20	
			27NOV2009	YES	5:45	YES	18:20	
			28NOV2009	YES	6:45	YES	18:40	
			29NOV2009	YES	6:30	YES	17:50	
			30NOV2009	YES	6:18	YES	18:10	
			01DEC2009	YES	8:00	YES	18:05	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	02DEC2009	YES	7:30	YES	18:25	
			03DEC2009	YES	6:30	YES	17:50	
			04DEC2009	YES	7:15	YES	17:45	
			05DEC2009	YES	7:15	YES	17:30	
			06DEC2009	YES	7:50	YES	17:50	
			07DEC2009	YES	8:00	YES	18:00	
			08DEC2009	YES	8:00	YES	17:55	
			09DEC2009	YES	7:50	YES	18:50	
			10DEC2009	YES	7:45	YES	18:05	
			11DEC2009	YES	8:00	YES	19:25	
			12DEC2009	YES	7:05	YES	18:50	
			13DEC2009	YES	7:45	YES	18:15	
			14DEC2009	YES	8:00	YES	18:05	
			15DEC2009	YES	7:55	YES	18:05	
			16DEC2009	YES	7:00			
			16DEC2009			YES	18:45	
			17DEC2009	YES	7:00	YES	18:20	
			18DEC2009	YES	7:05	YES	18:10	
			19DEC2009	YES	8:00	YES	17:55	
			20DEC2009	YES	8:15	YES	18:05	
			21DEC2009	YES	7:35	YES	18:05	
			22DEC2009	YES	7:40	YES	18:05	
			23DEC2009	YES	7:45	YES	18:40	
			24DEC2009	YES	7:10	YES	18:45	
			25DEC2009	YES	7:45	YES	18:30	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	26DEC2009	YES	8:25	YES	19:10	
			27DEC2009	YES	7:50	YES	18:30	
			28DEC2009	YES	8:10	YES	18:00	
			29DEC2009	YES	7:35	YES	18:05	14:30 - Kati steht vor der Schlafzimmertür und hat ein Gerät gebracht (Trimmrad)
			30DEC2009	YES	8:20	YES	19:35	Nachts ein schwarzes Tier rausgelassen Unruhe
			31DEC2009	YES	7:40	YES	19:55	07:30 ein Tier hat in seine Schuhe gesch., wir haben Ungeziefer, beim Essen 13:00 einen Hund gesehen
			01JAN2010	YES	9:15	YES	18:20	22:00 2 Igel gesehen. Strickjacke im Fenster eingeklemmt da war ein Tier
			02JAN2010	YES	8:10	YES	18:05	23:00 Tiere gesehen und aus dem Schlafzimmerfenster entfernt
			03JAN2010	YES	8:30	YES	18:20	
			04JAN2010	YES	8:10	YES	18:00	
			05JAN2010	YES	6:50	YES	18:25	04:10 mich geweckt. 06:00 wollte er nach New York, Tasche gepackt, getragene Sachen
			06JAN2010	YES	7:10	YES	18:05	
			07JAN2010	YES	8:30	YES	18:25	
			08JAN2010	YES	8:00	YES	18:05	03:30 geweckt, er sucht Toilette + Bett
			09JAN2010	YES	8:00	YES	18:15	nachm. er erkennt sein zu Hause nicht bis 23:00 Uhr
			10JAN2010	YES	7:45	YES	18:45	08:00 er hat im Hotel geschlafen. 18:00 im Wohnz. war jemand + neben ihm auf dem Sofa

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	11JAN2010	YES	8:10	YES	18:25	07:30 mit gepackten Taschen auf dem Bett gesessen, 22:30 ich soll ein Taxi bestellen, er will in die Heimat
			12JAN2010	YES	8:15	YES	17:30	Aufnahme Krankenhaus P1
			13JAN2010	YES	7:10	YES	17:35	
			14JAN2010	YES	7:00	YES	17:30	08:15 Pat. such sein Zi. SD Pat. beging mehrfach Fehlhandlung u. war desorient.
			15JAN2010	YES	7:20	YES	17:30	07:00 Pat. verwirrt. 10:30 Pat. Ø orientiert macht Fehlhandlungen <- SD. SD Pat. kam unbekleidet auf d. Stationf.
			16JAN2010	YES	7:10	YES	17:30	FD. Pat. desorientiert. SD Fehlhandlungen und desorientiert.
			17JAN2010	YES	7:20	YES	17:30	FD. Pat. begeht Fehlhandlungen, desorientiert. SD Fehlhandlungen und desorientiert.
			18JAN2010	YES	7:05	YES	17:30	FD: Pat. begeht mehrfach Fehlhandlungen
			19JAN2010	YES	7:10	YES	17:45	FD: Pat. begeht etwas weniger Fehlhandlungen als gestern. SD teilweise Fehlhandlungen hat gespiel -> adäquat.
			20JAN2010	YES	7:00	YES	17:35	FD Pat. desorientiert. SD war viel in Begleitung Angehöriger außer Station, beim Abendbrot durcheinander.
			21JAN2010	YES	7:15	YES	18:30	Pat. begeht Fehlhandlungen u. desorientiert. Pat. begeht weiterhin Fehlhandlungen.
			22JAN2010	YES	7:10	YES	17:30	FD Pat. desorientiert Fehlhandlungen. Pat. begeht Fehlhandlgg. nett, frdl. -> desorientiert.

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	23JAN2010	YES	7:15	YES	17:30	Pat. desorientiert, macht Fehlhandlungen/Pat. unverändert.
			24JAN2010	YES	7:15	YES	17:30	Pat. Ø Fehlhandlungen
			25JAN2010	YES	7:10	YES	17:30	FD - 07:00 Pat. etwas verwirrt, kommt alleine gar nicht zurecht. Pat. recht ruhig, begeht weiterhin Fehlhandlg.
			26JAN2010	YES	7:10	YES	17:30	FD. Pat. begeht Fehlhandlg. ist desorientiert. Pat. ruhiger, weniger Fehlhandlungen, ztw. adäquat.
			27JAN2010	YES	7:00	YES	17:30	FD. Pat - brauchte Hilfe beim Duschen + Kleiden, ist etwas verwirrt. SD Pat. ist unverändert, begeht weiterh. Fehlhandlungen
			28JAN2010	YES	7:00	YES	17:35	FD Fehlhandlungen desorientiert. SD Hatte Besuch schien etwas orientierter
			29JAN2010	YES	7:00	YES	17:30	FD Pat. ist geordneter. SD Pat. beging tlw. Fehlhandlungen. Hatte Besuch v. Gattin
			30JAN2010	YES	7:10	YES	17:30	FD desorientiert, Fehlhand.
			31JAN2010	YES	7:10	YES	17:15	FD geordneter auch im Gespräch. SD Pat. ist niedergestimmt.
			01FEB2010	YES	7:10	YES	17:00	FD sehr durcheinander, eingenäßt, vollständige Übernahme Pflege
			02FEB2010	YES	7:30	YES	17:00	FD Bew. ist orientiert, gibt klare Anweisungen. SD auch so.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	03FEB2010	YES	7:30	YES	17:00	FD. - BW orientiert, macht klare Aussagen, äußert klare Wünsche. SD: BW orientiert geht aber zu spät zur Toilette
			04FEB2010	YES	7:30	YES	17:00	FD. - BW leicht verwirrt, die Handlungen verlangsamt zwischendurch klare Aussagen. SD.: BW leicht unorientiert, nimmt gern Hilfe an
			05FEB2010	YES	7:30	YES	17:00	FD: BW orientiert. SD. Die Handlungen sehr verlangsamt. Oberkörper stark nach vorne gebeugt. Gegen Abend hat in die Ecke Beläge gesehen
			06FEB2010	YES	7:30	YES	17:00	SD BW orientiert, klare Aussagen
			07FEB2010	YES	7:30	YES	17:30	Bew. eingenässt, soweit orientiert
			08FEB2010	YES	7:30	YES	17:00	SD. BW viel im Zimmer, komm kaum raus.
			09FEB2010	YES	7:30	YES	17:00	FD. BW im Zimmer, zieht sich aus und dann wieder an, kann das nicht erklären.
			10FEB2010	YES	7:00			
			10FEB2010			YES	16:30	SD: Bew. zieht sich in sein Zimmer zurück. Bew:
			11FEB2010	YES	7:30	YES	16:30	SD: Bew. gut orientiert, fremdes Bett
			12FEB2010	YES	7:30			Bew. ist etwas desorientiert -> konnte sein Zim. nicht finden, legt sich in ein fremden Bett hin.
			12FEB2010	YES	7:30	YES	16:30	Bew. war sehr ruhig und entspannt, hat gut gegessen + getrunken, wollte um 19.00 ins Bett, fragte, wo er schläft
			13FEB2010	YES	7:30	YES	16:30	FD: Bew. gut drauf + orientiert. SD: Bew. ist gut drauf

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	14FEB2010	YES	7:30	YES	16:30	FD: Bew. gut orientiert und fröhlich. SD: Bew. gut orientiert sehr gut gelaunt.
			15FEB2010	YES	7:30	YES	16:30	FD: Bew. gut gelaunt, aber schlecht orientiert. SD: Bew. war fröhlich aber nicht orientiert
			16FEB2010	YES	7:30	YES	17:00	FD: Bew. war sehr durcheinander und wußte nicht, wie und was er anziehen sollte.
			17FEB2010	YES	7:30	YES	16:30	SD: Bew. war PK sehr anhänglich.
			18FEB2010	YES	7:30	YES	16:30	SD: Bew. was sehr durcheinander.
			19FEB2010	YES	7:30	YES	17:00	
			20FEB2010	YES	7:30	YES	16:30	Bew. hat das Zimmer einuriniert SD: Bew. legt sich viel in fremde Betten.
			21FEB2010	YES	7:30	YES	16:30	Bew. kann sich nicht merken wo sein Zimmer ist liegt oft im fremden Bett.
			22FEB2010	YES	7:30	YES	16:30	Bew. desorientiert, findet sein Zimmer nicht, geht in die anderen Zimmer. Bew. sehr desorientiert.
			23FEB2010	YES	7:30	YES	17:00	FD: Bew. sehr desorientiert, suchte immer sein Zimmer.
			24FEB2010	YES	7:30	YES	16:30	Bew. desorientiert, geht im Zimmer ziellos herum. SD: Bew. ist sehr desorientiert, nimmt es aber mit Humor.
			25FEB2010	YES	7:30	YES	16:30	FD -> zieht sich ständig aus. SD: weiß nicht, wie er sich wieder anziehen soll, wo er hin muß, wo sein Zimmer ist.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	26FEB2010	YES	7:30	YES	16:30	FD: Bew. desorientiert, sucht ständig sein Zimmer, auch wenn gerade da raus kommt. Weiß aber die Nummer von seinem Zimmer. SD: Dito
			27FEB2010	YES	7:30	YES	16:30	FD: Bew. sehr desorientiert, weiß nicht wohin, geht sehr krumm, macht sich selten gerade. SD: Bew. desorientiert.
			28FEB2010	YES	7:30	YES	16:30	FD: Bew. läuft gegen Türen, Fenster, Sofa, etc. SD: Bew. desorientiert.
			01MAR2010	YES	7:30	YES	16:30	Bew. desorientiert, zieht sich aus und läuft auf d. WB ohne Bekleidung. SD: Bew. total desorientiert.
			02MAR2010	YES	7:30	YES	16:30	Bew. findet sein Zimmer nicht. BW hatte Halluzinationen ein Hund hat seinen Saft getrunken.
			03MAR2010	YES	7:30	YES	16:30	FD: Bew. weiterhin desorientiert.
			04MAR2010	YES	7:30	YES	20:30	FD: Bew. entkleidet sich und findet Zi. nicht wieder. Bew. war zur Versorgung im KH (nach Sturz) sucht vergebl. WC.
			05MAR2010	YES	7:30	YES	16:30	FD: Bew. gut drauf. BW hat große Schwierigkeiten sich hinzusetzen, ist unkoordiniert, setzt sich daneben.
			06MAR2010	YES	7:30	YES	16:30	Bew. war eingenässt, wollte immer seine Frau anrufen.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	07MAR2010	YES	8:00	YES	16:30	Bew. kann kaum laufen bevor er Tablette nimmt danach etwas besser, BW neigt mit OK stark nach vorne zu beugen, ist sehr sturzgefährdet.
			08MAR2010	YES	7:30	YES	16:30	Bew. findet sein Zimmer nicht allein. Bew. sehr desorientiert, findet sein Zimmer nicht.
			09MAR2010	YES	7:30	YES	16:30	BW geht ziellos auf d. WB I, ist sehr anhängig am PK. SD: BW findet Zimmer.
			10MAR2010	YES	7:30	YES	16:30	Bew. kann Anweisungen nicht umsetzen. SD: BW kann teilweise die Anweisung von PK nicht umsetzen, z.B. hinsetzen auf d. Bettkante, Beine hochnehmen.
			11MAR2010	YES	7:30	YES	16:30	FD: Bew. wusste nicht, wie er auf die Toilette gehen soll. Umsetzen von Anweisung klappt erst beim 2., 3. Mal.
			12MAR2010	YES	7:30	YES	16:30	FD: BW kann aufrecht gehen, ist orientiert, war zum Gedächtnistraining. Gegen 11.30 BW konnte nicht mehr die Anweisungen umsetzen.
			12MAR2010					SD: Bew. konnte Anweisungen nicht umsetzen. Brauchte 3 Aufforderungen zum Hinsetzen.
			13MAR2010	YES	7:30	YES	16:30	FD: Bew. gut drauf, hat aber Schwierigkeiten Anw. umzusetzen. Bew. war durcheinander und sehr schläfrig.
			14MAR2010	YES	7:30	YES	16:30	Bew. konnte seine Schuhe nicht wieder finden und suchte noch andere Dinge.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	15MAR2010	YES	7:30	YES	17:00	BW ist zeitlich + örtlich desorientiert, hatte Schwierigkeiten beim reden. War verwirrt. SD: genauso.
			16MAR2010	YES	7:30	YES	16:30	BW schläft sehr viel, kann nicht allein vom Bett aufstehen. SD: Bew. kann keine Anweisung umsetzen.
			17MAR2010	YES	7:30	YES	16:30	FD: BW war mobil hat aber Schwierigkeit umzusetzen wie er trinken soll. SD: BW gut drauf + mobil.
			18MAR2010	YES	7:30	YES	16:30	FD: BW mobil, motiviert war b. Gottesdienst, ist an PK anhängig, kann aufrecht gehen, ist wacher.
			19MAR2010	YES	7:30			FD: BW ist mobil, läuft viel auf d. WB, kann aber die Anweisungen nicht umsetzen, teilweise nicht ausführen.
			19MAR2010			YES	16:30	Bew. sieht überall kleine "Wäscheklammer Osterhasen", hat PK viele gezeigt. Halluziniert.
			20MAR2010	YES	7:30	YES	16:30	Bew. ist mobil auf WB bleibt stehen und weiß nicht was er weiter machen soll. SD: genauso.
			21MAR2010	YES	7:30	YES	16:30	BW desorientiert.
			22MAR2010	YES	7:30	YES	16:30	BW geht ziellos auf d. WB, zieht sich im Zimmer aus kann nicht erklären warum. SD: weiß nicht wie er trinken soll.
			23MAR2010	YES	7:30	YES	16:30	FD: Bew. war viel auf d. WB unterwegs, hat Schwierigkeiten mit Koordination z.B. beim hinsetzen. SD: Koordinationsprobleme.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	24MAR2010	YES	7:30	YES	16:30	SD: Bew. hat Koordinationsprobleme, läuft sehr nach vorne gebeugt.
			25MAR2010	YES	7:30	YES	16:30	SD: Bew. ist unkoordiniert -> zittert mit den Händen, kann manchmal kaum einen Becher halten.
			26MAR2010	YES	7:30	YES	16:30	FD: Bew. Koordinations- und Orientierungsprobleme. Bew. hat Schwierigkeiten einen Becher zu halten.
			27MAR2010	YES	7:30	YES	16:30	FD: Bew. hat Probleme beim halten von Gegenständen und zittert mit den Händen.
			28MAR2010	YES	7:30	YES	16:30	Bew. hat starkes Zittern der rechten Hand und kann Anweisungen nicht ums.
			29MAR2010	YES	7:30	YES	16:30	Bew. besser drauf, als am WE. Hat viel gesprochen, gegessen und gelaufen.
			30MAR2010	YES	7:30	YES	16:30	Bew. zieht sich mehrmals komplett aus und merkt nicht, dass er ausgezogen ist.
			31MAR2010	YES	7:30	YES	16:30	Bew. kann sein Zimmer nicht finden, wenn er im Zimmer ist, geht er wieder raus und sucht das Zimmer.
			01APR2010	YES	7:30	YES	16:30	Bew. kann Anweisungen schlecht umsetzen. Er muss ständig zur Toilette.
			02APR2010	YES	7:20	YES	16:30	Lt. NW ist Bew. seit 04:00 auf und irrt auf dem WB herum, dabei entkleidet er sich stetig.
			03APR2010	YES	7:30	YES	16:30	Bew. war schon wach um 06:00. Bew. verwirrt, weiß nicht, wo er ist, war eingenässt.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	04APR2010	YES	7:30	YES	16:30	Bew. zieht sich mehrmals am Tage aus, findet sich nicht zurecht.
			05APR2010	YES	7:30	YES	16:30	Bew. Hände zittern sehr stark.
			06APR2010	YES	7:30	YES	16:30	Bew. sehr durcheinander, weiß nicht, was er machen soll. Bew. Hände zittern stark.
			07APR2010	YES	7:30	YES	16:30	Bew. desorientiert. Findet sein Zimmer nicht. Denkt er ist im Hotel.
			08APR2010	YES	7:30	YES	16:30	Bew. zieht sich mehrmals am Tage die Kleidung aus.
			09APR2010	YES	7:30	YES	16:30	Bew. ganz gut drauf.
			10APR2010	YES	7:30	YES	16:30	FD: Bew. läuft ziellos über den Flur, legt sich in fremde Betten!
			11APR2010		7:30	YES	16:30	Bew. ist örtlich unorientiert, Aussprache klar u. deutlich. Hände zittern heute.
			12APR2010	YES	7:30	YES	16:30	Bew. unruhig. Hände zittern, örtlich unorientiert.
			13APR2010	YES	7:30	YES	16:30	Bew. läuft viel herum. Örtlich nicht orientiert. Findet sein Zimmer nicht.
			14APR2010	YES	7:30	YES	16:36	Bew. läuft viel herum. Bew. findet sein Zimmer nicht.
			15APR2010	YES	7:30	YES	16:30	Bew. ist sehr durcheinander, will immer nach Elmsh. und erläutern. Ist 2x vom WB gelaufen.
			16APR2010	YES	7:30	YES	16:30	SD BW zuerst unauffällig -> nach d. Abendbrot war er entsetzt, dass er hier schlafen muss. Er hat das noch nie gemacht.
			17APR2010	YES	7:30	YES	16:30	SD verwirrt, geht in fremde Zimmer rein, versteht nicht, dass es nicht seins ist.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	18APR2010	YES	7:30	YES	16:30	SD BW ist verwirrt, geht in d. fremde Zimmer rein, findet seins nicht, ist sehr an PK anhängig.
			19APR2010	YES	7:30	YES	16:30	Fr. BW ist ganzen Vormittag mobil, geht ins fremde Zimmer rein, und sagt, dass es seins ist.
			20APR2010	YES	7:30	YES	16:30	Bew. nässt sich wiederholt ein, findet sein Zimmer nicht.
			21APR2010	YES	7:30	YES	16:30	Bew. findet sein Zimmer nicht, Hände zittern stark bei den Mahlzeiten.
			22APR2010	YES	7:30	YES	16:30	Bew. völlig unorientiert, kippt beim Gehen stark nach rechts. Geht sehr schleppend.
			23APR2010	YES	7:30	YES	16:30	Bew. ist mobil, aber unorientiert. Bew. hat Rechtsdrall alles, wenn er nach rechts weg kippt und war angeh.
			24APR2010	YES	7:30	YES	16:30	Mobil auf WB unterwegs. Bew. halluziniert, ist teilw. aggressiv und nicht orientiert.
			25APR2010	YES	7:30	YES	16:30	Bew. mobil, aber unorientiert. Bew. sehr unruhig, nicht orientiert, verliert leicht die Geduld.
			26APR2010	YES	7:30	YES	16:30	Bew. nicht orientiert.
			27APR2010	YES	7:30	YES	16:30	BW ist mobil -> geht im Garten spazieren, ist trotztd. desorientiert, kann sein Zim. nicht finden.
			28APR2010	YES	7:30	YES	16:30	Bew. kotete sich und das Badezimmer ein.
			29APR2010	YES	7:30	YES	16:30	SD: BW kann d. Anweisungen nicht verstehen. Beim hinsetzen ist er sehr steif. Zeitweise ist er verzweifelt.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	30APR2010	YES	7:30	YES	16:30	FD: BW kann heute schlecht trinken. Hat Probleme es umzusetzen, was PK sagt.
			30APR2010			YES	16:30	RR niedrig, P niedrig, ist ins Krankenhaus eingeliefert werden - Pat. hat Probleme Info umzusetzen.
			01MAY2010	YES	7:30			Pat. hat Schwierigkeiten beim Trinken, kann Gesagtes schwer umsetzen.
			01MAY2010			YES	16:30	Pat. schläft, auf Ansprache wach, Pat. war eingenässt u - eingekotet, Tabl. eingen. dann weiter geschlafen.
			02MAY2010	YES	7:30	YES	16:30	Pat. schläft immer wieder ein. Pat. geht mit Begleitung zur Toilette u. sitzt an der Bettkante für 1/2 Std. dann kippt Pat. immer nach hinten weg.
			03MAY2010	YES	7:30		16:30	
			04MAY2010	YES	7:30	YES	16:30	
			05MAY2010	YES	7:30	YES	16:30	
			06MAY2010	YES	7:30			
			07MAY2010	YES	7:30	YES	16:30	Bew. sehr durcheinander.
			08MAY2010	YES	7:30	YES	16:30	Bew. war sehr desorientiert.
			09MAY2010	YES	8:00	YES	16:30	Bew. war sehr schläfrig.
			10MAY2010	YES	7:30	YES	16:30	Bew. ruhig, auf d. WB mobil.
			11MAY2010	YES	7:30	YES	16:30	Bew. ist sehr schläfrig. War auf d. WB nur kurze Zeit mobil. Bew. zog sich 3x aus.
			12MAY2010	YES	7:30			

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	12MAY2010	YES	7:30	YES	16:30	
			13MAY2010	YES	7:30	YES	16:30	
			14MAY2010	YES	7:30	YES	16:30	
			15MAY2010	YES	7:30	YES	16:30	SD BW war sehr viel unterwegs auf d. WB I. Gang aufrecht, Blick starr.
			16MAY2010	YES	7:30	YES	16:30	FD Bew. hat sich 4 mal entkleidet.
			17MAY2010	YES	7:30	YES	16:30	Bew. fühlt sich alleine nicht wohl. Ist die meiste Zeit in der Nähe vom PK gewesen.
			18MAY2010	YES	7:30	YES	16:30	SD: Starkes Zittern der Hände. BW entkleidet sich.
			19MAY2010	YES	7:30	YES	16:30	SD: Bew. ist wach, geht viel auf WB, auch im Garten. Sein Zimmer findet er nicht.
			20MAY2010	YES	7:30	YES	16:30	Bew. hat Bewegungsdrang, ist viel mobil. Kann nicht lange sitzen, auch b. Essen, steht permanent auf.
			21MAY2010	YES	7:30	YES	16:30	Kann Anweisungen kaum umsetzen, findet sein Zimmer nicht. Sehr mobil.
			22MAY2010	YES	7:30	YES	16:30	BW schläfrig, BW hat sich eingenässt. BW zittert, findet sein Zi. nicht.
			23MAY2010	YES	7:30	YES	16:30	BW findet Zi. nicht, liegt im anderen Bett u. schläft.. BW hat sich einmal entkleidet -> wusste nicht warum.
			24MAY2010	YES	7:30	YES	16:30	BW findet Zi. nicht liegt im fremden Bett u. schläft.
			25MAY2010	YES	7:30	YES	16:30	Bew. unorientiert, zieht sich wiederholt aus.
			26MAY2010	YES	7:30	YES	16:30	Bew. findet sein Zimmer nicht.

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ACI-91	043	12	27MAY2010	YES	7:30	YES	16:30	
			28MAY2010	YES	7:30	YES	16:30	Bew. sehr unruhig findet sein Zimmer nicht legt sich in fremde Betten, entkleidet sich oft.
			29MAY2010	YES	7:30	YES	16:30	Pat. ist orientierungslos. Findet Zi. Ø.
			30MAY2010	YES	7:30	YES	16:30	
			31MAY2010	YES	7:30	YES	16:30	
			01JUN2010	YES	7:30	YES	16:30	
			02JUN2010	YES	7:30	YES	16:30	Bew. viel unterwegs, zieht sich aus.
			03JUN2010	YES	7:30	YES	16:30	Bew. sehr fröhlich sitzt im Garten, kann Tasse nicht alleine halten.
			04JUN2010	YES	7:30	YES	16:30	Bew. kann sich nicht alleine hinsetzen und nicht alleine aufstehen.
			05JUN2010	YES	7:30	YES	16:30	Bew. viel unterwegs, findet sein Zi. nicht.
			06JUN2010	YES	7:30	YES	16:30	Bew. war es zu heiß draußen -> sein Zi., abends findet er sein Zi. nicht.
			07JUN2010	YES	7:30	YES	16:30	Bew. hat sich die meiste Zeit im Zimmer aufgehalten TV gesehen.
			08JUN2010	YES	7:30	YES	16:30	Bew. sehr früh wach, aufgeregt, dass er ins KH soll.
			09JUN2010	YES	7:30	YES	16:30	Pat. wach, ruhig. Pat. hat momentan ein EEG.
								20:00 Pat. sehr schläfrig den SD über.
			10JUN2010	YES	7:30	YES	16:30	Pat. wach_ gibt adäquat Antwort, liegt im Bett.
								18:00 Pat. läßt viel Urin, ist wach.
			11JUN2010	YES	7:30	YES	16:30	Pat. wach, verwirrt, läuft orientierungslos umher -> FD.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	12JUN2010	YES	7:30	YES	16:30	BW mobil hat selbstständig Fernseher angemacht.
			13JUN2010	YES	7:30	YES	16:30	
			14JUN2010	YES	7:30	YES	16:30	Bew. verwirrt, nicht sein Zimmer, Bew. ist mobil auf Station.
			15JUN2010	YES	7:30	YES	16:30	Bew. ruft ständig um Hilfe, ist dann aber nichts.
			16JUN2010	YES	7:30	YES	16:30	
			17JUN2010	YES	7:30	YES	16:30	Bew. sehr aktiv auf Wohnb. durcheinander.
			18JUN2010	YES	7:30	YES	16:30	
			19JUN2010	YES	7:15	YES	16:30	Bew. aktiv + desorientiert.
			20JUN2010	YES	7:30	YES	16:30	Bew. sehr desorientiert.
			21JUN2010	YES	7:30	YES	16:30	
			22JUN2010	YES	7:30	YES	16:30	
			23JUN2010	YES	7:30	YES	16:30	
			24JUN2010	YES	7:30	YES	16:30	
			25JUN2010	YES	7:36	YES	16:30	
			26JUN2010	YES	7:30	YES	16:30	
			27JUN2010	YES	7:30	YES	16:30	Bew. hat sich mehrfach ausgezogen.
			28JUN2010	YES	7:30	YES	16:30	Bew. ist unruhig.
			29JUN2010	YES	7:30	YES	16:30	Bew. kann Anweisungen schlecht bis gar nicht umsetzen.
			30JUN2010			YES	16:30	Bew. kann keine Anweisung umsetzen.
			01JUL2010	YES	7:30	YES	16:30	Bew. hat viel geschlafen.
			02JUL2010	YES	7:30	YES	16:30	Bew. schläft zwischendurch, kann Anweisungen schlecht bis gar nicht umsetzen.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	03JUL2010	YES	7:30	YES		Bew. kann Anweisungen nicht umsetzen, legt sich mehrfach in fremde Betten.
			04JUL2010	NO		YES		Ausgelassen wg. AZ, Bew. schläft.
			05JUL2010	YES	7:30	NO		Bew. unruhig und durcheinander.
			06JUL2010	NO		YES	16:30	
			07JUL2010	YES	7:25	YES	18:30	Gut führbar, gute Beweglichkeit - gute Beweglichkeit, nicht gut führbar.
			08JUL2010	YES	7:30	YES	16:30	Gut führbar, aber sehr unruhig! Bew. schläft.
			09JUL2010	YES	7:30	YES	16:30	
			10JUL2010	YES		YES	16:30	
			11JUL2010	YES	7:30	YES	16:30	Bew. ist örtl. nicht orientiert, unruhig.
			12JUL2010	YES	7:30	YES	16:30	Bew. sehr schläfrig, kann kaum laufen, neigt zur li Seite zu kippen.
			13JUL2010	YES	7:30	YES	16:30	BW kann kaum gehen, Essen musste gereicht werden. Bew. sehr schläfrig.
			14JUL2010	YES	7:30	YES		Bew. auf d. WB I mobil, hat sich in d. Betten von anderen BW rein gelegt, war viel wach.
			15JUL2010	YES	7:30	YES	16:30	Bew. sehr schläfrig.
			16JUL2010	YES	7:30		17:30	Bew. ist unruhig und schläfrig. Essen allein. Bew. kann Anweisungen nicht umsetzen.
			17JUL2010	YES	7:30	YES	16:30	Bew. sehr unruhig. Bew. sehr unsicher auf d. Beinen, müde.
			18JUL2010	YES	7:30	YES	16:30	Bew. wackelig und unsicher auf den Beinen.
			19JUL2010	YES	7:30	YES	16:30	Bew. sehr schlapp, schläfrig, konnte nicht selbstständig essen und trinken.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	20JUL2010	YES	7:30	YES	16:30	BW sehr schläfrig, kaum ansprechbar. Bew. sehr schwach und schlapp.
			21JUL2010	YES	7:30	YES	16:30	Bew. ist sehr müde, schläft sehr viel, lässt sich oft fallen.
			22JUL2010	YES	7:30	YES	16:30	
			23JUL2010	YES	7:30	YES	16:30	BW schläft nur.
			24JUL2010	YES	7:30	YES	16:30	Bew. schläfrig und stark nach re. geneigt.
			25JUL2010	YES	7:30	YES	16:30	Bew. schläft nur AZ, Infusion angelegt, im Bett gelagert.
			26JUL2010			YES	16:30	
			27JUL2010	YES	7:30	YES	16:30	
			28JUL2010	YES	7:30	YES	16:30	
			29JUL2010	YES	7:30			Bew. wird zu den Mahlzeiten in RS mobilisiert.
			30JUL2010	YES	7:30	YES	16:30	
			31JUL2010	YES	7:30	YES	16:30	Bew. kann Anweisungen nicht umsetzen, AZ schwach.
			01AUG2010	YES	7:50	YES	16:30	Bew. ist etwas orientierter, AZ schwach.
			02AUG2010	YES	7:30	YES	16:30	Bew. schläft viel. AZ schwach.
			03AUG2010	YES	7:30	YES	16:30	AZ schwach, Bew. ist schläfrig. Mittags sehr aktiv im PIS.
			04AUG2010	YES	7:30	YES	16:30	AZ schwach. Bew. versucht wieder aufzustehen.
			05AUG2010	YES	7:30	YES	16:30	
			06AUG2010	YES	7:00	YES	16:30	AZ wird besser, Bew. versucht selber zu trinken.
			07AUG2010	YES	7:00	YES	16:30	Bew. ist mobil, steht auf und geht auf d. WB.
			08AUG2010	YES	7:00	YES	16:30	Bew. ist sehr schwach kann nicht alleine aufstehen. Starker Tremor.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	043	12	09AUG2010	YES	7:00	YES	16:30	AZ schwach.
			10AUG2010	YES	7:00	YES	16:30	Bew. war wach aber konnte Anweisungen nicht umsetzen. AZ schwach, sehr schläfrig.
			11AUG2010	YES	7:30			AZ schwach, sehr schläfrig. Abbruch der Medi.-Gabe, nicht möglich.
	046	11	16APR2000	YES	7:00	YES	18:00	
			18APR2000	YES	7:00	YES	18:00	
			11JAN2010			YES	19:00	
			12JAN2010	YES	8:00	YES	18:00	
			13JAN2010	YES	7:30	YES	18:00	
			14JAN2010	YES	7:30	YES	18:00	
			15JAN2010	YES	7:30	YES	18:00	
			16JAN2010	YES	7:30	YES	18:00	
			17JAN2010	YES	7:30	YES	18:00	
			18JAN2010	YES	7:30	YES	18:00	
			19JAN2010	YES	7:30	YES	18:00	
			20JAN2010	YES	7:30	YES	18:00	
			21JAN2010	YES	7:30	YES	18:30	
			22JAN2010	YES	8:30	YES	18:00	
			23JAN2010	YES	7:00	YES	18:00	
			24JAN2010	YES	7:30	YES	18:00	
			25JAN2010	YES	7:30	YES	18:00	
			26JAN2010	YES	7:00	YES	18:30	
			27JAN2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	28JAN2010	YES	7:30	YES	18:30	
			29JAN2010	YES	7:30	YES	18:30	
			30JAN2010	YES	7:30	YES	18:00	
			31JAN2010	YES	7:30	YES	18:00	
			01FEB2010	YES	7:30	YES	18:00	
			02FEB2010	YES	7:30	YES	18:00	
			03FEB2010	YES	7:30	YES	18:00	
			04FEB2010	YES	7:00	YES	18:00	
			05FEB2010	YES	7:30	YES	18:30	
			06FEB2010	YES	7:30	YES	18:30	
			07FEB2010	YES	7:30	YES	18:00	
			08FEB2010	YES	7:00			
			08FEB2010			YES	18:30	
			09FEB2010	YES	7:30	YES	18:00	
			10FEB2010	YES	7:30	YES	18:00	
			11FEB2010	YES	7:30	YES	18:00	
			12FEB2010	YES	7:30	YES	18:00	
			13FEB2010	YES	7:30	YES	18:00	
			14FEB2010	YES	7:30	YES	18:00	
			15FEB2010	YES	7:30	YES	18:00	
			16FEB2010	YES	7:30	YES	18:00	
			17FEB2010	YES	7:30	YES	18:00	
			18FEB2010	YES	7:30	YES	18:00	
			19FEB2010	YES	7:30	YES	18:00	
			20FEB2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	21FEB2010	YES	7:30	YES	18:00	
			22FEB2010	YES	7:30	YES	18:00	
			23FEB2010	YES	7:30	YES	18:00	
			24FEB2010	YES	7:30	YES	18:00	
			25FEB2010	YES	7:30	YES	18:00	
			26FEB2010	YES	7:30	YES	18:00	
			27FEB2010	YES	7:00	YES	18:00	
			28FEB2010	YES	7:00	YES	18:00	
			01MAR2010	YES	7:00	YES	18:00	
			02MAR2010	YES	7:00	YES	18:00	
			03MAR2010	YES	7:00	YES	18:00	
			04MAR2010	YES	7:00	YES	18:30	
			05MAR2010	YES	7:00	YES	18:30	
			06MAR2010	YES	7:00	YES	18:30	
			07MAR2010	YES	7:00	YES	18:30	
			08MAR2010	YES	7:00	YES	18:30	
			09MAR2010	YES	7:00	YES	18:00	
			10MAR2010	YES	7:00	YES	18:00	
			11MAR2010	YES	7:00	YES	18:00	
			12MAR2010	YES	7:00	YES	18:00	
			13MAR2010	YES	7:00	YES	18:00	
			14MAR2010	YES	7:00	YES	18:00	
			15MAR2010	YES	7:00	YES	18:00	
			16MAR2010	YES	7:00	YES	18:00	
			17MAR2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	18MAR2010	YES	7:00	YES	18:00	
			19MAR2010	YES	7:00	YES	18:00	
			20MAR2010	YES	7:00	YES	18:00	
			21MAR2010	YES	7:00	YES	18:00	
			22MAR2010	YES	7:00	YES	18:00	
			23MAR2010	YES	7:00	YES	18:00	
			24MAR2010	YES	7:00	YES	18:00	
			25MAR2010	YES	7:00	YES	18:00	
			26MAR2010	YES	7:00	YES	18:00	
			27MAR2010	YES	7:00	YES	18:00	
			28MAR2010	YES	7:00	YES	18:00	
			29MAR2010	YES	7:00	YES	18:00	
			30MAR2010	YES	7:00	YES	18:00	
			31MAR2010	YES	7:00	YES	18:00	
			01APR2010	YES	7:00	YES	18:00	
			02APR2010	YES	7:00	YES	18:00	
			03APR2010	YES	7:00	YES	18:00	
			04APR2010	YES	7:00	YES	18:00	
			05APR2010	YES	7:00	YES	18:00	
			06APR2010	YES	7:00	YES	18:00	
			07APR2010	YES	7:00			
			07APR2010			YES	18:00	
			08APR2010	YES	7:00	YES	18:00	
			09APR2010	YES	7:00	YES	18:00	
			10APR2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	11APR2010	YES	7:00	YES	18:00	
			12APR2010	YES	7:00	YES	18:00	
			13APR2010	YES	7:00	YES	18:00	
			14APR2010	YES	7:00	YES	18:00	
			15APR2010	YES	7:00	YES	18:00	
			17APR2010	YES	7:00	YES	18:00	
			19APR2010	YES	7:00	YES	18:00	
			20APR2010	YES	7:00	YES	18:00	
			21APR2010	YES	7:00	YES	18:00	
			22APR2010	YES	7:00	YES	18:00	
			23APR2010	YES	7:00	YES	18:00	
			24APR2010	YES	7:00	YES	18:00	
			25APR2010	YES	7:00	YES	18:00	
			26APR2010	YES	7:00	YES	18:00	
			27APR2010	YES	7:00	YES	18:00	
			28APR2010	YES	7:00	YES	18:00	
			29APR2010	YES	7:00	YES	18:00	
			30APR2010	YES	7:00	YES	18:00	
			01MAY2010	YES	7:00	YES	18:00	
			02MAY2010	YES	7:00	YES	18:00	
			03MAY2010	YES	7:00	YES	18:00	
			04MAY2010	YES	7:00	YES	18:00	
			05MAY2010	YES	7:00	YES	18:00	
			06MAY2010	YES	7:00	YES	18:00	
			07MAY2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	08MAY2010	YES	7:00	YES	18:00	
			09MAY2010	YES	7:00	YES	18:00	
			10MAY2010	YES	7:00	YES	18:00	
			11MAY2010	YES	7:00	YES	18:00	
			12MAY2010	YES	7:00	YES	18:00	
			13MAY2010	YES	7:00	YES	18:00	
			14MAY2010	YES	7:00	YES	18:00	
			15MAY2010	YES	7:00	YES	18:00	
			16MAY2010	YES	7:00	YES	18:00	
			17MAY2010	YES	7:00	YES	18:00	
			18MAY2010	YES	7:00	YES	18:00	
			19MAY2010	YES	7:00	YES	18:00	
			20MAY2010	YES		YES	18:00	
			21MAY2010	YES		YES	18:00	
			22MAY2010	YES	7:00	YES	19:00	
			23MAY2010	YES	7:00	YES	19:00	
			24MAY2010	YES	7:00	YES	19:00	
			25MAY2010	YES	7:00	YES	19:00	
			26MAY2010	YES	7:00	YES	19:00	
			27MAY2010	YES	7:00	YES	19:00	
			28MAY2010	YES	7:00	YES	19:00	
			29MAY2010	YES	7:00	YES	19:00	
			30MAY2010	YES	7:00	YES	19:00	
			31MAY2010	YES	7:00	YES	19:00	
			01JUN2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	02JUN2010	YES	7:00	YES	19:00	
			03JUN2010	YES	7:00	YES	19:00	
			04JUN2010	YES	7:00	YES	19:00	
			05JUN2010	YES	7:00	YES	19:00	
			06JUN2010	YES	7:00	YES	19:00	
			07JUN2010	YES	7:00	YES	19:00	
			08JUN2010	YES	7:00	YES	19:00	
			09JUN2010	YES	7:00	YES	19:00	
			10JUN2010	YES	7:00	YES	19:00	
			11JUN2010	YES	7:00	YES	19:00	
			12JUN2010	YES	7:00	YES	19:00	
			13JUN2010	YES	7:00	YES	19:00	
			14JUN2010	YES	7:00	YES	19:00	
			15JUN2010	YES	7:00	YES	19:00	
			16JUN2010	YES	7:00	YES	19:00	
			17JUN2010	YES	7:00	YES	19:00	
			18JUN2010	YES	7:00	YES	19:00	
			19JUN2010	YES	7:00	YES	19:00	
			20JUN2010	YES	7:00	YES	19:00	
			21JUN2010	YES	7:00	YES	19:00	
			22JUN2010	YES	7:00	YES	19:00	
			23JUN2010	YES	7:00	YES	19:00	
			24JUN2010	YES	7:00	YES	19:00	
			25JUN2010	YES	7:00	YES	19:00	
			26JUN2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	27JUN2010	YES	7:00	YES	18:00	
			28JUN2010	YES	7:00	YES	18:00	
			29JUN2010	YES	7:00	YES	18:00	
			30JUN2010	YES	7:00	YES	18:00	
			01JUL2010	YES	7:00	YES	18:00	
			02JUL2010	YES	7:00	YES	18:00	
			03JUL2010	YES	7:00	YES	18:00	
			04JUL2010	YES	7:00	YES	18:00	
			05JUL2010	YES	7:00	YES	18:00	
			06JUL2010	YES	7:00	YES	18:00	
			07JUL2010	YES	7:00			
			07JUL2010			YES	18:00	
			08JUL2010	YES	7:00	YES	18:00	
			09JUL2010	YES	7:00	YES	18:00	
			10JUL2010	YES	7:00	YES	18:00	
			11JUL2010	YES	7:00	YES	18:00	
			12JUL2010	YES	7:00	YES	18:00	
			13JUL2010	YES	7:00	YES	18:00	
			14JUL2010	YES	7:00	YES	18:00	
			15JUL2010	YES	7:00	YES	18:00	
			16JUL2010	YES	7:00	YES	18:00	
			17JUL2010	YES	7:00	YES	18:00	
			18JUL2010	YES	7:00	YES	18:00	
			19JUL2010	YES	7:00	YES	18:00	
			20JUL2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	21JUL2010	YES	7:00	YES	18:00	
			22JUL2010	YES	7:00	YES	18:00	
			23JUL2010	YES	7:00	YES	18:00	
			24JUL2010	YES	7:00	YES	18:00	
			25JUL2010	YES	7:00	YES	18:00	
			26JUL2010	YES	7:00	YES	18:00	
			27JUL2010	YES	7:00	YES	18:00	
			28JUL2010	YES	7:00	YES	18:00	
			29JUL2010	YES	7:00	YES	18:00	
			30JUL2010	YES	7:00	YES	18:00	
			31JUL2010	YES	7:00	YES	18:00	
			01AUG2010	YES	7:00	YES	18:00	
			02AUG2010	YES	7:00	YES	18:00	
			03AUG2010	YES	7:00	YES	18:00	
			04AUG2010	YES	7:00	YES	18:00	
			05AUG2010	YES	7:00	YES	18:00	
			06AUG2010	YES	7:00	YES	18:00	
			07AUG2010	YES	7:00	YES	18:00	
			08AUG2010	YES	7:00	YES	18:00	
			09AUG2010	YES	7:00	YES		
			10AUG2010	YES	7:00	YES	18:00	
			11AUG2010	YES	7:00	YES	18:00	
			12AUG2010	YES	7:00	YES	17:00	
			13AUG2010	YES	7:00	YES	18:00	
			14AUG2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	15AUG2010	YES	7:00	YES	18:00	
			16AUG2010	YES	7:00	YES	18:00	
			17AUG2010	YES	7:00	YES	18:00	
			18AUG2010	YES	7:00	YES	18:00	
			19AUG2010	YES	7:00	YES	18:00	
			20AUG2010	YES	7:00	YES	18:00	
			21AUG2010	YES	7:00	YES	18:00	
			22AUG2010	YES	7:00	YES	18:00	
			23AUG2010	YES	7:00	YES	18:00	
			24AUG2010	YES	7:00	YES	18:00	
			25AUG2010	YES	7:00	YES	18:00	
			26AUG2010	YES	7:00	YES	18:00	
			27AUG2010	YES	7:00	YES	18:00	
			28AUG2010	YES	7:00	YES	18:00	
			29AUG2010	YES	7:00	YES	18:00	
			30AUG2010	YES	7:00	YES	18:00	
			31AUG2010	YES	7:00	YES	18:00	
			01SEP2010	YES	7:00	YES	18:00	
			02SEP2010	YES	7:00	YES	18:00	
			03SEP2010	YES	7:00	YES	18:00	
			04SEP2010	YES	7:00	YES	18:00	
			05SEP2010	YES	7:00	YES	18:00	
			06SEP2010	YES	7:00	YES	18:00	
			07SEP2010	YES	7:00	YES	18:00	
			08SEP2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	09SEP2010	YES	7:00	YES	18:00	
			10SEP2010	YES	7:00	YES	18:00	
			11SEP2010	YES	7:00	YES	18:00	
			12SEP2010	YES	7:00	YES	18:00	
			13SEP2010	YES	7:00	YES	18:00	
			14SEP2010	YES	7:00	YES	18:00	
			15SEP2010	YES	7:00	YES	18:00	
			16SEP2010	YES	7:00	YES	18:00	
			17SEP2010	YES	7:00	YES	18:00	
			18SEP2010	YES	7:00	YES	18:00	
			19SEP2010	YES	7:00	YES	18:00	
			20SEP2010	YES	7:00	YES	18:00	
			21SEP2010	YES	7:00	YES	18:00	
			22SEP2010	YES	7:00			
			22SEP2010			YES	18:00	
			23SEP2010	YES	7:00	YES	18:00	
			24SEP2010	YES	7:00	YES	18:00	
			25SEP2010	YES	7:00	YES	18:00	
			26SEP2010	YES	7:00	YES	18:00	
			27SEP2010	YES	7:00	YES	18:00	
			28SEP2010	YES	7:00	YES	18:00	
			29SEP2010	YES	7:00	YES	18:00	
			30SEP2010	YES	7:00	YES	18:00	
			01OCT2010	YES	7:00	YES	18:00	
			02OCT2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	03OCT2010	YES	7:00	YES	18:00	
			04OCT2010	YES	7:00	YES	18:00	
			05OCT2010	YES	7:00	YES	18:00	
			06OCT2010	YES	7:00	YES	18:00	
			07OCT2010	YES	7:00	YES	18:00	
			08OCT2010	YES	7:00	YES	18:00	
			09OCT2010	YES	7:00	YES	18:00	
			10OCT2010	YES	7:00	YES	18:00	
			11OCT2010	YES	7:00	YES	18:00	
			12OCT2010	YES	7:00	YES	18:00	
			13OCT2010	YES	7:00	YES	18:00	
			14OCT2010	YES	7:00	YES	18:00	
			15OCT2010	YES	7:00	YES	18:00	
			16OCT2010	YES	7:00	YES	18:00	
			17OCT2010	YES	7:00	YES	18:00	
			18OCT2010	YES	7:00	YES	18:00	
			19OCT2010	YES	7:00	YES	18:00	
			20OCT2010	YES	7:00	YES	18:00	
			21OCT2010	YES	7:00	YES	18:00	
			22OCT2010	YES	7:00	YES	18:00	
			23OCT2010	YES	7:00	YES	18:00	
			24OCT2010	YES	7:00	YES	18:00	
			25OCT2010	YES	7:00	YES	18:00	
			26OCT2010	YES	7:00	YES	18:00	
			27OCT2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	28OCT2010	YES	7:00	YES	18:00	
			29OCT2010	YES	7:00	YES	18:00	
			30OCT2010	YES	7:00	YES	18:00	
			31OCT2010	YES	7:00	YES	18:00	
			01NOV2010	YES	7:00	YES	18:00	
			02NOV2010	YES	7:00	YES	18:00	
			03NOV2010	YES	7:00	YES	18:00	
			04NOV2010	YES	7:00	YES	18:00	
			05NOV2010	YES	7:00	YES	18:00	
			06NOV2010	YES	7:00	YES	18:00	
			07NOV2010	YES	7:00	YES	18:00	
			08NOV2010	YES	7:00	YES	18:00	
			09NOV2010	YES	7:00	YES	18:00	
			10NOV2010	YES	7:00	YES	18:00	
			11NOV2010	YES	7:00	YES	18:00	
			12NOV2010	YES	7:00	YES	18:00	
			13NOV2010	YES	7:00	YES	18:00	
			14NOV2010	YES	7:00	YES	18:00	
			15NOV2010	YES	7:00	YES	18:00	
			16NOV2010	YES	7:00	YES	18:00	
			17NOV2010	YES	7:00	YES	18:00	
			18NOV2010	YES	7:00	YES	18:00	
			19NOV2010	YES	7:00	YES	18:00	
			20NOV2010	YES	7:00	YES	18:00	
			21NOV2010	YES	7:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	22NOV2010	YES	7:00	YES	18:00	
			23NOV2010	YES	7:00	YES	18:00	
			24NOV2010	YES	7:00	YES	18:00	
			25NOV2010	YES	7:00	YES	18:00	
			26NOV2010	YES	7:00	YES	18:00	
			27NOV2010	YES	7:00	YES	18:00	
			28NOV2010	YES	7:00	YES	18:00	
			29NOV2010	YES	7:00	YES	18:00	
			30NOV2010	YES	7:00	YES	18:10	
			01DEC2010	YES	7:00	YES	18:00	
			02DEC2010	YES	7:00	YES	18:00	
			03DEC2010	YES	7:00	YES	18:00	
			04DEC2010	YES	7:00	YES	18:00	
			05DEC2010	YES	7:00	YES	18:00	
			06DEC2010	YES	7:00	YES	18:00	
			07DEC2010	YES	7:00	YES	18:00	
			08DEC2010	YES	7:00	YES	18:00	
			09DEC2010	YES	7:00	YES	18:00	
			10DEC2010	YES	7:00	YES	18:00	
			11DEC2010	YES	7:00	YES	18:00	
			12DEC2010	YES	7:00	YES	18:00	
			13DEC2010	YES	7:00	YES	18:00	
			14DEC2010	YES	7:00	YES	18:00	
			15DEC2010	YES	7:00	YES	18:00	
			16DEC2010	YES	7:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	17DEC2010	YES	7:00	YES	18:00	
			18DEC2010	YES	7:00	YES	18:00	
			19DEC2010	YES	7:00	YES	18:00	
			20DEC2010	YES	7:00	YES	18:00	
			21DEC2010	YES	7:00	YES	18:00	
			22DEC2010	YES	7:00	YES	18:00	
			23DEC2010	YES	7:00	YES	18:00	
			24DEC2010	YES	7:00	YES	18:00	
			25DEC2010	YES	7:00	YES	18:00	
			26DEC2010	YES	7:00	YES	18:00	
			27DEC2010	YES	7:00	YES	18:00	
			28DEC2010	YES	7:00	YES	18:00	
			29DEC2010	YES	7:00	YES	18:00	
			30DEC2010	YES	7:00	YES	18:00	
			31DEC2010	YES	7:00	YES	18:00	
			01JAN2011	YES	7:00	YES	18:00	
			02JAN2011	YES	7:00	YES	18:00	
			03JAN2011	YES	7:00	YES	18:00	
			04JAN2011	YES	7:00	YES	18:00	
			05JAN2011	YES	7:00	YES	18:00	
			06JAN2011	YES	7:00	YES	18:00	
			07JAN2011	YES	7:00	YES	18:00	
			08JAN2011	YES	7:00	YES	18:00	
			09JAN2011	YES	7:00	YES	18:00	
			10JAN2011	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	046	11	11JAN2011	YES	7:00	YES	18:00	
			12JAN2011	YES	7:00			
	048	11	22NOV2010			YES	19:50	
			23NOV2010	YES	9:15	YES	19:00	
			24NOV2010	YES	9:00	YES	18:00	
			25NOV2010	YES	9:30	YES	19:45	
			26NOV2010	YES	9:00	YES	17:50	
			27NOV2010	YES	8:30	YES	17:15	
			28NOV2010	YES	8:10	YES	18:35	
			29NOV2010	YES	8:10	YES	18:15	
			30NOV2010	YES	9:10	YES	17:35	
			01DEC2010	YES	8:30	YES	17:25	
			02DEC2010	YES	8:45	YES	20:55	
			03DEC2010	YES	8:30	YES	19:30	
			04DEC2010	YES	8:50	YES	15:55	
			05DEC2010	YES	8:30	YES	18:30	
			06DEC2010	YES	7:45	YES	16:45	
			07DEC2010	YES	8:30	YES	17:15	
			08DEC2010	YES	8:55	YES	20:50	
			09DEC2010	YES	8:50	YES	20:55	
			10DEC2010	YES	7:15	YES	20:40	
			11DEC2010	YES	9:15	YES	18:30	
			12DEC2010	YES	9:30	YES	21:05	
			13DEC2010	YES	8:45	YES	18:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	14DEC2010	YES	8:30	YES	19:40	
			15DEC2010	YES	8:45	YES	19:15	
			16DEC2010	YES	8:45	YES	21:25	
			17DEC2010	YES	7:45	YES	17:30	
			18DEC2010	YES	9:15	YES	15:15	
			19DEC2010	YES	10:30	YES	18:10	
			20DEC2010	YES	8:45	YES	17:10	
			21DEC2010	YES	7:10			
			21DEC2010			YES	19:40	Tübingen
			22DEC2010	YES	9:30	YES	16:45	
			23DEC2010	YES	8:50	YES	20:30	
			24DEC2010	YES	9:05	YES	17:30	
			25DEC2010	YES	7:30	YES	21:15	
			26DEC2010	YES	8:15	YES	18:00	
			27DEC2010	YES	8:55	YES	16:50	
			28DEC2010	YES	9:00	YES	18:30	
			29DEC2010	YES	8:55	YES	19:25	
			30DEC2010	YES	8:25	YES	16:15	
			31DEC2010	YES	9:20	YES	16:30	
			01JAN2011	YES	9:15	YES	19:55	
			02JAN2011	YES	9:15	YES	17:00	
			03JAN2011	YES	9:10	YES	18:45	
			04JAN2011	YES	9:00	YES	17:30	
			05JAN2011	YES	8:15	YES	18:00	
			06JAN2011	YES	9:15	YES	19:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	07JAN2011	YES	8:15	YES	19:05	
			08JAN2011	YES	9:10	YES	19:10	
			09JAN2011	YES	8:50	YES	18:30	
			10JAN2011	YES	8:45	YES	20:30	
			11JAN2011	YES	8:35	YES	17:35	
			12JAN2011	YES	9:10	YES	18:30	
			13JAN2011	YES	8:55	YES	19:35	
			14JAN2011	YES	8:50	YES	17:55	
			15JAN2011	YES	9:15	YES	17:30	
			16JAN2011	YES	9:10	YES	17:10	
			17JAN2011	YES	8:55	YES	16:30	
			18JAN2011	YES	8:45	YES	17:45	
			19JAN2011	YES	9:10	YES	17:55	
			20JAN2011	YES	9:15	YES	17:30	
			21JAN2011	YES	8:55	YES	19:15	
			22JAN2011	YES	8:50	YES	17:15	
			23JAN2011	YES	8:30	YES	18:25	
			24JAN2011	YES	8:45	YES	18:45	
			25JAN2011	YES	8:50	YES	19:15	
			26JAN2011	YES	9:15	YES	18:10	
			27JAN2011	YES	9:00	YES	17:20	
			28JAN2011	YES	8:30	YES	18:00	
			29JAN2011	YES	9:05	NO		
			30JAN2011	YES	9:45	YES	16:45	
			31JAN2011	YES	10:00	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	01FEB2011	YES	8:50	YES	18:15	
			02FEB2011	YES	8:45	YES	18:10	
			03FEB2011	YES	9:30	YES	19:10	
			04FEB2011	YES	8:55	YES	21:10	
			05FEB2011	YES	9:15	YES	20:15	
			06FEB2011	YES	9:45	YES	17:45	
			07FEB2011	YES	9:55	YES	17:45	
			08FEB2011	YES	9:30	YES	18:20	
			09FEB2011	YES	9:45	YES	17:15	
			10FEB2011	YES	8:30	YES	19:50	
			11FEB2011	YES	8:30	YES	19:10	
			12FEB2011	YES	8:15	YES	19:30	
			13FEB2011	YES	8:50	YES	17:05	
			14FEB2011	YES	8:45	YES	17:15	
			15FEB2011	YES	6:15			
			15FEB2011			YES	17:25	
			16FEB2011	YES	8:15	YES	17:45	
			17FEB2011	YES	8:05	YES	20:30	
			18FEB2011	YES	8:30	YES	18:30	
			19FEB2011	YES	9:15	YES	19:15	
			20FEB2011	YES	8:50	YES	18:30	
			21FEB2011	YES	7:05	YES	18:15	
			22FEB2011	YES	8:45	YES	17:45	
			23FEB2011	YES	7:45	YES	19:10	
			24FEB2011	YES	8:05	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	25FEB2011	YES	8:15	YES	18:30	
			26FEB2011	YES	7:45	YES	17:55	
			27FEB2011	YES	8:15	YES	18:15	
			28FEB2011	YES	7:55	YES	22:30	
			01MAR2011	YES	8:45	YES	17:30	
			02MAR2011	YES	8:15	YES	20:50	
			03MAR2011	YES	8:45	YES	18:25	
			04MAR2011	YES	7:50	YES	17:30	
			05MAR2011	YES	7:55	YES	18:45	
			06MAR2011	YES	7:55	YES	23:45	
			07MAR2011	YES	9:30	YES	17:05	
			08MAR2011	YES	8:00	YES	20:20	
			09MAR2011	YES	7:50	YES	18:45	
			10MAR2011	YES	8:15	YES	17:45	
			11MAR2011	YES	8:15	YES	17:15	
			12MAR2011	YES	8:45	YES	18:00	
			13MAR2011	YES	8:05	YES	18:15	
			14MAR2011	YES	8:00	YES	17:15	
			15MAR2011	YES	8:35	YES	18:20	
			16MAR2011	YES	8:40	YES	18:35	
			17MAR2011	YES	8:15	YES	17:15	
			18MAR2011	YES	8:25	YES	17:10	
			19MAR2011	YES	9:30	YES	17:45	
			20MAR2011	YES	8:25	YES	18:45	
			21MAR2011	YES	8:05	NO		Vergessen!

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	22MAR2011	YES	8:30	YES	20:30	
			23MAR2011	YES	7:45	YES	18:30	
			24MAR2011	YES	8:40	YES	19:55	
			25MAR2011	YES	8:00	YES	20:00	
			26MAR2011	YES	9:30	NO		Vergessen!
			27MAR2011	YES	10:00	YES	18:30	
			28MAR2011	YES	10:50	YES	19:15	
			29MAR2011	YES	8:15	YES	21:55	
			30MAR2011	YES	8:35	YES	20:30	
			31MAR2011	YES	9:25	YES	17:55	
			01APR2011	YES	8:10	YES	18:45	
			02APR2011	YES	8:55	YES	20:45	
			03APR2011	YES	8:40	YES	19:45	
			04APR2011	YES	9:10	YES	19:45	
			05APR2011	YES	8:50	YES	18:15	
			06APR2011	YES	8:35	YES	20:15	
			07APR2011	YES	8:15	YES	17:30	
			08APR2011	YES	8:10	YES	18:15	
			09APR2011	YES	9:05	YES	19:35	
			10APR2011	YES	8:35	YES	17:05	
			11APR2011	YES	8:50	YES	19:45	
			12APR2011	YES	8:55	YES	18:50	
			13APR2011	YES	9:15	YES	19:10	
			14APR2011	YES	8:40	YES	19:30	
			15APR2011	YES	7:55	YES	18:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	16APR2011	YES	8:15	NO		Vergessen!
			17APR2011	YES	8:45	YES	19:50	
			18APR2011	YES	9:05	YES	18:15	
			19APR2011	YES	8:30	YES	17:20	
			20APR2011	YES	8:05	YES	20:30	
			21APR2011	YES	8:30	YES	18:15	
			22APR2011	YES	7:50	YES	17:45	
			23APR2011	YES	8:15	YES	18:30	
			24APR2011	YES	8:55	YES	19:50	
			25APR2011	YES	7:45	YES	17:05	
			26APR2011	YES	7:45	YES	19:30	
			27APR2011	YES	8:40	YES	20:55	
			28APR2011	YES	7:45	YES	19:50	
			29APR2011	YES	8:55	YES	17:45	
			30APR2011	YES	8:25	YES	18:45	
			01MAY2011	YES	9:30	YES	21:30	
			02MAY2011	YES	8:05	YES	17:05	
			03MAY2011	YES	8:15	YES	17:30	
			04MAY2011	YES	8:50	YES	16:30	
			05MAY2011	YES	9:05	YES	19:25	
			06MAY2011	YES	8:40	YES	18:15	
			07MAY2011	YES	8:30	YES	19:15	
			08MAY2011	YES	8:50	YES	18:25	
			09MAY2011	YES	8:45	YES	17:10	
			10MAY2011	YES	8:25	YES	18:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	11MAY2011	YES	8:50	YES	18:40	
			12MAY2011	YES	7:50	YES	20:00	
			13MAY2011	YES	8:30	YES	18:55	
			14MAY2011	YES	8:50	YES	18:45	
			15MAY2011	YES	8:50	YES	20:30	
			16MAY2011	YES	6:10			
			16MAY2011			YES	20:30	Termin in Tübingen Anfang Abends
			17MAY2011	YES	8:30	YES	20:45	
			18MAY2011	YES	8:10	YES	18:30	
			19MAY2011	YES	9:15	YES	18:50	
			20MAY2011	YES	8:40	YES	19:30	
			21MAY2011	YES	8:45	YES	20:50	
			22MAY2011	YES	8:50	YES	17:25	
			23MAY2011	YES	8:15	YES	18:05	
			24MAY2011	YES	8:45	YES	18:05	
			25MAY2011	YES	8:25	YES	17:10	
			26MAY2011	YES	8:30	YES	18:15	
			27MAY2011	YES	7:50	YES	19:45	
			28MAY2011	YES	8:30	YES	19:50	
			29MAY2011	YES	9:10	YES	19:15	
			30MAY2011	YES	8:45	YES	17:05	
			31MAY2011	YES	7:30	YES	19:10	
			01JUN2011	YES	7:45	YES	18:15	
			02JUN2011	YES	7:50	YES	17:05	
			03JUN2011	YES	8:30	YES	18:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	04JUN2011	YES	8:10	YES	19:15	
			05JUN2011	YES	8:45	YES	18:10	
			06JUN2011	YES	8:25	YES	17:55	
			07JUN2011	YES	8:15	YES	18:55	
			08JUN2011	YES	8:30	YES	20:30	
			09JUN2011	YES	7:55	YES	17:15	
			10JUN2011	YES	8:15	YES	19:10	
			11JUN2011	YES	8:45	YES	18:05	
			12JUN2011	YES	9:10	YES	19:45	
			13JUN2011	YES	9:05	YES	18:45	
			14JUN2011	YES	8:50	YES	17:45	
			15JUN2011	YES	8:25	YES	17:05	
			16JUN2011	YES	8:45	YES	20:30	
			17JUN2011	YES	8:05	YES	17:30	
			18JUN2011	YES	8:30	YES	19:20	
			19JUN2011	YES	8:45	YES	19:30	
			20JUN2011	YES	8:15	YES	19:50	
			21JUN2011	YES	8:05	YES	18:15	
			22JUN2011	YES	8:45	YES	20:30	
			23JUN2011	YES	8:35	YES	20:20	
			24JUN2011	YES	8:10	YES	17:25	
			25JUN2011	YES	7:55	YES	20:15	
			26JUN2011	YES	8:35	YES	16:50	
			27JUN2011	YES	7:25	YES	18:50	
			28JUN2011	YES	8:10	YES	18:45	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	29JUN2011	YES	7:10	YES	21:10	
			30JUN2011	YES	8:45	YES	21:45	
			01JUL2011	YES	7:10	YES	18:50	
			02JUL2011	YES	9:30			Vergessen abends!
			03JUL2011	YES	9:05	YES	18:05	
			04JUL2011	YES	8:30	YES	19:15	
			05JUL2011	YES	8:05		18:15	
			06JUL2011	YES	8:50	YES	20:30	
			07JUL2011	YES	8:15	YES	17:30	
			08JUL2011	YES	8:30	YES	19:15	
			09JUL2011	YES	8:20	YES	17:10	
			10JUL2011	YES	8:50	YES	19:10	
			11JUL2011	YES	8:15	YES	18:35	
			12JUL2011	YES	7:45	YES	20:35	
			13JUL2011	YES	8:10	YES	17:45	
			14JUL2011	YES	8:35	YES	21:35	
			15JUL2011	YES	8:40	YES	17:45	
			16JUL2011	YES	8:05	YES	17:30	
			17JUL2011	YES	8:55	YES	21:10	
			18JUL2011	YES	8:50	YES	18:10	
			19JUL2011	YES	8:30	YES	18:50	
			20JUL2011	YES	9:15	YES	19:15	
			21JUL2011	YES	8:50	YES	18:05	
			22JUL2011	YES	8:50	YES	19:10	
			23JUL2011	YES	8:25	YES	18:25	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	24JUL2011	YES	10:05	YES	17:05	
			25JUL2011	YES	8:50	YES	19:10	
			26JUL2011	YES	6:10			
			26JUL2011			YES	17:20	Tübingen!
			27JUL2011	YES	8:35	YES	21:45	
			28JUL2011	YES	8:50	YES	20:35	
			29JUL2011	YES	8:30	YES	20:30	
			30JUL2011	YES	9:50	YES	19:30	
			31JUL2011	YES	8:40	YES	19:15	
			01AUG2011	YES	8:20	YES	17:05	
			02AUG2011	YES	8:45	YES	17:30	
			03AUG2011	YES	8:10	YES	20:55	
			04AUG2011	YES	8:40	YES	18:10	Krankenhausaufenthalt!
			05AUG2011	YES	7:30	YES	17:25	starke, langanhaltende Kreislaufprobleme mit Erbrechen
			06AUG2011	YES	7:15	YES	20:55	Do-abend Einlieferung Sa-mittag Entlassung
			07AUG2011	YES	8:45	YES	16:30	
			08AUG2011	YES	8:30	YES	19:10	
			09AUG2011	YES	8:40	YES	19:45	
			10AUG2011	YES	8:25	YES	21:50	
			11AUG2011	YES	8:10	YES	17:30	
			12AUG2011	YES	7:40	YES	19:15	
			13AUG2011	YES	8:20	YES	19:25	
			14AUG2011	YES	8:55	YES	20:15	
			15AUG2011	YES	8:30	YES	18:10	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	16AUG2011	YES	8:45	YES	20:00	
			17AUG2011	YES	8:15	YES	18:30	
			18AUG2011	YES	8:20	YES	21:10	
			19AUG2011	YES	8:30	YES	19:15	
			20AUG2011	YES	8:50	YES	19:00	
			21AUG2011	YES	8:35	YES	21:40	
			22AUG2011	YES	8:30	YES	19:15	
			23AUG2011	YES	8:05	YES	18:30	
			24AUG2011	YES	8:35	YES	18:15	
			25AUG2011	YES	8:45	YES	19:45	
			26AUG2011	YES	8:20	YES	21:15	
			27AUG2011	YES	8:35	YES	18:10	
			28AUG2011	YES	8:30	YES	17:45	
			29AUG2011	YES	8:15	YES	19:35	
			30AUG2011	YES	8:10	YES	19:10	
			31AUG2011	YES	8:50	YES	19:45	
			01SEP2011	YES	8:30	YES	17:30	
			02SEP2011	YES	8:15	YES	18:10	
			03SEP2011	YES	8:45	YES	19:45	
			04SEP2011	YES	9:15	YES	17:10	
			05SEP2011	YES	8:15	YES	20:50	
			06SEP2011	YES	7:55	YES	19:45	
			07SEP2011	YES	8:15	YES	18:40	
			08SEP2011	YES	7:50	YES	17:45	
			09SEP2011	YES	8:25	YES	18:50	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	10SEP2011	YES	8:05	YES	19:15	
			11SEP2011	YES	8:30	YES	18:10	
			12SEP2011	YES	8:25	YES	17:30	
			13SEP2011	YES	8:05	YES	17:45	
			14SEP2011	YES	7:55	YES	18:15	
			15SEP2011	YES	8:15	YES	19:50	
			16SEP2011	YES	8:05	YES	17:50	
			17SEP2011	YES	8:30	YES	17:45	
			18SEP2011	YES	9:30	YES	19:55	
			19SEP2011	YES	8:15	YES	18:45	
			20SEP2011	YES	8:50	YES	20:15	
			21SEP2011	YES	7:50	YES	19:10	
			22SEP2011	YES	8:35	YES	19:10	
			23SEP2011	YES	8:35	YES	19:50	
			24SEP2011	YES	6:50	NO	22:00	
			25SEP2011	YES	9:50	YES	19:45	
			26SEP2011	YES	8:30	YES	18:10	
			27SEP2011	YES	8:35	YES	18:15	
			28SEP2011	YES	8:45	YES	17:45	
			29SEP2011	YES	8:40	YES	18:00	
			30SEP2011	YES	8:15	YES	21:00	
			01OCT2011	YES	8:30	YES	18:30	
			02OCT2011	YES	9:00	YES	19:00	
			03OCT2011	YES	8:00	YES	20:15	
			04OCT2011	YES	8:45	YES	19:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	05OCT2011	YES	8:30	YES	20:30	
			06OCT2011	YES	8:45	YES	17:40	
			07OCT2011	YES	8:15	YES	16:45	
			08OCT2011	YES	8:45	YES	18:30	
			09OCT2011	YES	7:50	YES	18:15	
			10OCT2011	YES	8:40	YES	19:10	
			11OCT2011	YES	8:10	YES	18:50	
			12OCT2011	YES	8:20	YES	18:30	
			13OCT2011	YES	9:10	YES	19:45	
			14OCT2011	YES	8:45	YES	18:50	
			15OCT2011	YES	8:15	YES	17:55	
			16OCT2011	YES	8:40	YES	18:45	
			17OCT2011	YES	8:30	YES	17:15	
			18OCT2011	YES	8:45	YES	18:10	
			19OCT2011	YES	8:50	YES	19:15	
			20OCT2011	YES	8:45	YES	18:50	
			21OCT2011	YES	8:30	YES	19:15	
			22OCT2011	YES	8:50	YES	20:15	
			23OCT2011	YES	9:15	YES	18:10	
			24OCT2011	YES	8:45	YES	19:10	
			25OCT2011	YES	8:25	YES	18:30	
			26OCT2011	YES	8:45	YES	16:30	
			27OCT2011	YES	8:50	YES	17:45	
			28OCT2011	YES	8:15	YES	19:30	
			29OCT2011	YES	8:45	YES	16:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	048	11	30OCT2011	YES	8:50	YES	16:30	
			31OCT2011	YES	8:45	YES	17:15	
			01NOV2011	YES	8:10	YES	18:30	
			02NOV2011	YES	8:45	YES	20:10	
			03NOV2011	YES	7:45	YES	17:45	
			04NOV2011	YES	8:10	YES	19:45	
			05NOV2011	YES	9:15	YES	19:30	
			06NOV2011	YES	9:15	YES	18:10	
			07NOV2011	YES	8:30	YES	18:50	
			08NOV2011	YES	7:45	YES	19:35	
			09NOV2011	YES	7:45	YES	17:45	
			10NOV2011	YES	8:15	YES	19:30	
			11NOV2011	YES	8:45	YES	20:00	
			12NOV2011	YES	6:30	YES	21:55	
			13NOV2011	YES	9:45	YES	18:45	
			14NOV2011	YES	8:25	YES	20:05	
			15NOV2011	YES	8:10	YES	19:10	
			16NOV2011	YES	6:45			Tübingen
	050	21	01NOV2000	YES	7:00			
			28OCT2010	YES	6:55	YES	18:00	1 Tablette !!?
			29OCT2010	YES	7:40	YES	17:30	Kopfschmerzen "Stechen"
			30OCT2010	YES	6:35	YES	18:00	
			31OCT2010	YES	7:15	YES	17:45	
			02NOV2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	03NOV2010	YES		YES		
			04NOV2010	YES		YES		
			05NOV2010	YES		YES		
			06NOV2010	YES		YES		
			13NOV2010	YES	7:00	YES	17:00	
			14NOV2010	YES	7:30			
			22NOV2010	YES	7:30	YES	20:30	Kein Kopfweh
			23NOV2010	YES	6:45	YES	17:30	Kopf weh u. Kopf stechen
			24NOV2010	YES	6:30	YES	17:45	Kopf stechen, unvoll, impfen gegen Grippe
			25NOV2010	YES	6:45	YES	17:30	Kopfstechen
			26NOV2010	YES	6:20	YES	18:00	Nacht Kopfstechen + Kopfweh, Schwindel
			27NOV2010	YES	6:50	YES	17:00	Kopfweh schon morgens
			28NOV2010	YES	7:15	YES	18:30	Nervös + grreits
			29NOV2010	YES	6:15	YES	19:15	Kopfweh
			30NOV2010	YES	7:05	YES	18:00	Kopfweh u. Kopfstecken
			01DEC2010	YES	6:45	YES	17:40	Kopfstechen
			02DEC2010	YES	7:00	YES	17:30	Kopfstechen, Kopfweh
			03DEC2010	YES	6:45	YES	17:45	Kopfstechen
			04DEC2010	YES	7:10	YES	18:10	Kopfweh, Müde
			05DEC2010	YES	6:30	YES	17:00	Übelkeit, Kopfstechen
			06DEC2010	YES	6:50	YES	17:20	Müdigkeit
			07DEC2010	YES	7:15	YES	17:50	Kopfweh, Kopfstechen, Einkaufen
			08DEC2010	YES	6:40	YES	18:00	Besuch bei Schwester Cilli, Kopfschmerzen
			09DEC2010	YES	7:10	YES	17:30	Kopfstecken, Unwohl, Kopfweh
			10DEC2010	YES	7:30	YES	19:30	Kopfschmerzen

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	11DEC2010	YES	6:50	YES	17:40	Unwohl, Kopfstechen
			12DEC2010	YES	7:10	YES	18:00	Kopfschmerzen
			13DEC2010	YES	6:30	YES	17:10	Müheikeit
			14DEC2010	YES	6:50	YES	18:10	Kopfweh
			15DEC2010	YES	6:30	YES	17:45	
			16DEC2010	YES	6:45	YES	17:50	
			17DEC2010	YES	7:05	YES	17:30	
			18DEC2010	YES	7:20	YES	19:00	
			19DEC2010	YES	7:15	YES	18:00	
			20DEC2010	YES	6:50	YES	18:10	
			21DEC2010	YES	7:30	YES	19:00	
			22DEC2010	YES	6:45	YES	17:40	Kopfstechen, Kopfweh "Föhn"
			23DEC2010	YES	6:50	YES	18:10	Kopfweh
			24DEC2010	YES	8:10	YES	18:50	
			25DEC2010	YES	6:45	YES	16:30	
			26DEC2010	YES	7:30	YES	18:10	
			27DEC2010	YES	6:50	YES	17:30	
			28DEC2010	YES	6:50	YES	17:00	
			29DEC2010	YES	6:10	YES	18:10	
			30DEC2010	YES	6:45	YES	17:20	
			31DEC2010	YES	7:05	YES	18:10	
			01JAN2011	YES	8:00	YES	17:30	Kopfweh, Kopfstechen stark
			02JAN2011	YES	7:50	YES	18:10	Kopfstechen
			03JAN2011	YES	7:20	YES	17:55	Kopfweh, Kopfstechen stark
			04JAN2011	YES	6:30	YES	17:00	Kopfweh, Kopfstechen stark

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	05JAN2011	YES	7:10	YES	17:50	Kopfweh, Kopfstechen stark
			18JAN2011	YES	7:10	YES	17:20	
			19JAN2011	YES	7:15	YES	18:00	Kopfstechen, Kopfweh abends
			20JAN2011	YES	6:55	YES	17:40	Kopfweh sehr stark
			21JAN2011	YES	7:00	YES	17:50	Kopfstechen
			22JAN2011	YES	7:15	YES	19:00	Unwohl
			23JAN2011	YES	7:40	YES	18:10	
			24JAN2011	YES	6:50	YES	17:30	Kopfweh
			25JAN2011	YES	7:00	YES	18:00	Kopfstechen
			26JAN2011	YES	7:30	YES	18:30	
			27JAN2011	YES	6:30	YES	17:00	
			28JAN2011	YES	7:50	YES	17:30	Kopfweh, Kopfstechen
			29JAN2011	YES	6:50	YES	18:10	Kopfweh, Rückenschmerzen
			30JAN2011	YES	7:10	YES	18:00	Kopfweh, Kopfstechen, unwohl
			31JAN2011	YES	7:20	YES	17:55	Starke Kopfschmerzen am Morgen, Kopfweh auch abends
			01FEB2011	YES	7:00	YES	18:30	Kopfweh
			02FEB2011	YES	6:55	YES	17:20	Einschlaf-gefühl-Kopf-Arm-Füsse links, Kopfstechen den ganzen Tag
			03FEB2011	YES	7:10	YES	18:15	Einschlaf-gefühl-Kopf-Arm-Füsse links, Kopfstechen den ganzen Tag
			04FEB2011	YES	7:00	YES	17:40	Kopfstechen, Kopfweh
			05FEB2011	YES	7:10	YES	17:50	Kopfstechen, Kopfweh
			06FEB2011	YES	6:50	YES	18:00	Kopfstechen, Kopfweh
			07FEB2011	YES	7:00	YES	18:20	

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	08FEB2011	YES	7:20	YES	18:10	Kopfweh
			09FEB2011	YES	7:00	YES	18:30	
			10FEB2011	YES	7:20	YES	18:30	Starkes Kopfweh den ganzen Tag
			11FEB2011	YES	8:00	YES	17:20	Kopfstechen
			12FEB2011	YES	6:50	YES	18:10	
			13FEB2011	YES	7:10	YES	18:00	
			14FEB2011	YES	6:00	YES	17:30	Kopfweh, Knochenschmerzen
			15FEB2011	YES	6:50	YES	17:45	Kopfweh, Müdigkeit
			16FEB2011	YES	7:40	YES	17:30	Müdigkeit, Gelenkschmerzen
			17FEB2011	YES	6:55	YES	18:10	Zahnschmerzen, Zahnarzt
			18FEB2011	YES	6:50	YES	17:40	Kopfdruck, Kopfstechen
			19FEB2011	YES	7:15	YES	17:50	Gelenkschmerzen
			20FEB2011	YES	6:55	YES	18:10	
			21FEB2011	YES	7:05	YES	17:40	Kopfstechen, Kopfweh
			22FEB2011	YES	6:50	YES	18:00	
			23FEB2011	YES	6:50	YES	17:30	Kopfschmerzen, Gelenkschmerzen
			24FEB2011	YES	7:05	YES	18:10	Kopfschmerzen u. Wallungen von Kopf bis zu den Füßen 09:30
			25FEB2011	YES	7:00	YES	17:40	
			26FEB2011	YES	6:45	YES	18:10	Gelenkschmerzen, Kopfweh
			27FEB2011	YES	7:10	YES	18:20	Kopfstechen 10 h Wallungen von Kopf bis zu den Füßen
			28FEB2011	YES	7:15	YES	18:00	Starkes Kopfstechen
			01MAR2011	YES	5:40	YES	18:00	Zeitweise starkes Kopfstechen
			02MAR2011	YES	7:00	YES	17:50	Kopfstechen 11 h Wallungen am ganzen Körper

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	03MAR2011	YES	7:10	YES	18:00	Kopfstechen sehr stark
			04MAR2011	YES	6:55	YES	19:10	Kopfstechen sehr stark
			05MAR2011	YES	7:10	YES	19:10	Kopfweh
			06MAR2011	YES	6:50	YES	17:30	Kopfweh, Schmerzen in den Gelenken
			07MAR2011	YES	7:20	YES	18:10	Starke Kopfschmerzen und viel vergessen
			08MAR2011	YES	7:10	YES	17:50	Kopfschmerzen, Gelenkschmerzen, Krämpfe in den Händen
			09MAR2011	YES	7:00	YES	19:10	Kopfstechen
			10MAR2011	YES	7:30	YES	18:20	Kopfstechen, Kopfweh
			11MAR2011	YES	7:15	YES	17:50	Kopfweh und viel vergessen
			12MAR2011	YES	6:55	YES	17:20	Kopfweh
			13MAR2011	YES	7:15	YES	19:00	08:00 Sehr starkes Kopfstechen, 18:00 Kopfweh, anbrennen von Speisen
			14MAR2011	YES	6:30	YES	18:40	Kopfstechen, Krämpfe in den Armen
			15MAR2011	YES	7:00	YES	17:45	Kopfweh, Schwermütig!!
			16MAR2011	YES	7:10	YES	18:00	Kopfstechen
			17MAR2011	YES	7:10	YES	18:10	Kopfweh
			18MAR2011	YES	6:45	YES	17:55	Kopfweh
			19MAR2011	YES	7:30	YES	18:00	Sehr starkes Kopfstechen 11 h
			20MAR2011	YES	7:00	YES	18:20	Kopfweh den ganzen Tag
			21MAR2011	YES	6:45	YES	17:30	Kopfstechen sehr stark 10-16 h
			22MAR2011	YES	7:10	YES	18:30	Kopfstechen, Blasenschmerzen, Prakt. Arzt
			23MAR2011	YES	7:30	YES	17:50	Starkes Kopfweh
			24MAR2011	YES	6:40	YES	17:30	Kopfschmerzen am hinter Kopf sehr stark
			25MAR2011	YES	6:50	YES	17:50	Kopfweh, Gliederschmerzen Hände + Rücken

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	26MAR2011	YES	7:00	YES	18:10	Kopfweh, Kopfstechen den ganzen Tag
			27MAR2011	YES	7:50	YES	19:10	Kopfweh
			28MAR2011	YES	6:55	YES	18:20	Kopfweh
			29MAR2011	YES	7:10	YES	17:40	Kopfweh, Kopfstechen 8-13 h
			30MAR2011	YES	7:00	YES	18:30	Kopfstechen, Blasenschmerzen (Garten)
			31MAR2011	YES	7:00	YES	19:00	"Wanderung" Hüftschmerzen, Kopfweh ganzen Tag
			01APR2011	YES	7:30	YES	18:10	Kopfweh, Blasenschmerzen
			02APR2011	YES	7:10	YES	18:40	Starke Kopfschmerzen am Hinterkopf, unwohl am ganzen Körper
			03APR2011	YES	6:50	YES	17:30	Kopfweh
			04APR2011	YES	7:20	YES	17:40	Kopfstechen
			05APR2011					Keine Tabletten
			06APR2011					Keine Tabletten, Kopfstechen, Wanderung Arzler Alm
			07APR2011					Keine Tabletten, starkes Kopfstechen 7-12, Kopfschmerzen den ganzen Tag
			08APR2011					Keine Tabletten, starkes Kopfstechen, Kopfschmerzen
			09APR2011					Keine Tabletten, Kopfstechen, Kopfweh
			10APR2011					Keine Tabletten, Kopfweh
			11APR2011			YES	17:00	Kopfschmerzen
			12APR2011	YES	7:45	YES	18:10	Kopfstechen
			13APR2011	YES	7:10	YES	17:20	Kopfstechen, Magenschmerzen
			14APR2011	YES	7:00	YES	18:10	Kopfweh, schwermütig
			15APR2011	YES	7:20	YES	18:30	Leichtes Kopfstechen am Hinterkopf
			16APR2011	YES	6:50	YES	18:40	Kopfstechen am Hinterkopf

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	17APR2011	YES	7:20	YES	20:00	Kopfweh, Kopfstechen am Hinterkopf stark
			18APR2011	YES	7:50	YES	19:20	Kopfstechen schon morgens
			19APR2011	YES	7:30	YES	20:00	Kopfstechen stark, Kopfweh am Nachmittag
			20APR2011	YES	7:00	YES	18:00	Kopfstechen, Lebensmüde, Kopfweh
			21APR2011	YES	7:50	YES	18:20	Kopfstechen "Föhn", Blumen einsetzen "gut"
			22APR2011	YES	6:45	YES	17:50	Kopfweh - Abends
			23APR2011	YES	7:15	YES	18:00	Kopfstechen
			24APR2011	YES	6:55	YES	19:20	Kopfweh, Magenschmerzen
			25APR2011	YES	7:10	YES	18:00	Kopfweh
			26APR2011	YES	6:50	YES	18:20	Kopfweh
			27APR2011	YES	6:45	YES	18:00	Kopfstechen
			28APR2011	YES	7:05	YES		Starkes Kopfstechen
			29APR2011	YES	6:45	YES	18:10	Kopfstechen "vergesslich"
			30APR2011	YES	7:00	YES	17:30	Kopfstechen
			01MAY2011	YES	6:30	YES	18:00	Kopfstechen am Hinterkopf
			02MAY2011	YES	6:40	YES	17:45	Kopfweh
			03MAY2011	YES	7:05	YES	17:45	Kopfweh
			04MAY2011	YES	6:50	YES	18:05	Kopfweh
			05MAY2011	YES	7:00	NO		Kopfstechen, Übelkeit, Erbrechen am Nachmittag, Abends keine Tablette wegen Müdigkeit
			06MAY2011	NO		NO		Keine Tabletten wegen Erbrechen. Arztbesuch: Pantoloc 20 mg, Motilium 10 mg
			07MAY2011	YES	7:30	YES	18:10	Tabletten wie 06.05.2011, Kopfstechen
			08MAY2011	YES	6:45	YES	17:20	An Hinterkopf stechen
			09MAY2011	YES	7:00	YES	18:05	Leichtes Kopfstechen

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	10MAY2011	YES	7:20	YES	17:50	Leichtes Kopfstechen
			11MAY2011	YES	6:40	YES	17:30	Kopfweh, Kopfstechen "stark"
			12MAY2011	YES	6:50	YES	18:05	Kopfstechen, vergesslich
			13MAY2011	YES	7:00	YES	18:05	Leichtes Kopfstechen
			14MAY2011	YES	6:45	YES	17:40	Leichtes Kopfstechen
			15MAY2011	YES	6:50	YES	18:10	Kopfweh
			16MAY2011	YES	6:45	YES	18:00	Sehr starkes Kopfstechen
			17MAY2011	YES	8:00	YES	17:50	Starkes Kopfstechen
			18MAY2011	YES	6:40	YES	18:00	Kopfstechen
			19MAY2011	YES	6:45	YES	19:00	Sehr starkes Kopfstechen am Hinterkopf
			20MAY2011	YES	7:10	YES	18:00	Kopfstechen
			21MAY2011	YES	6:50	YES	17:50	Kopfstechen
			22MAY2011	YES	6:45	YES	18:20	Starkes Kopfstechen am Kopf
			23MAY2011	YES	6:50	YES	19:20	Kopfweh
			24MAY2011	YES	7:10	YES	18:40	Kopfweh, Müdigkeit
			25MAY2011	YES	6:30	YES	17:30	Klinik wegen Blase!! Kopfstechen und Müdigkeit
			26MAY2011	YES	7:10	YES	18:00	Kopfweh, leichtes Kopfstechen
			27MAY2011	YES	6:10	YES	17:20	Kopfstechen
			28MAY2011	YES	6:50	YES	17:30	Kopfstechen
			29MAY2011	YES	7:00	YES	19:00	Kopfstechen, unwohl
			30MAY2011	YES	6:50	YES	18:20	Starkes Kopfstechen
			31MAY2011	YES	7:00	YES	17:40	Kopfstechen
			01JUN2011	YES	6:30	YES	18:20	Kopfstechen
			02JUN2011	YES	6:50	YES	18:30	Föhnig, Kopfweh
			03JUN2011	YES	7:05	YES	17:50	Kopfstechen

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	04JUN2011	YES	6:00	YES	17:10	Kopfstechen
			05JUN2011	YES	7:20	YES	18:30	Föhn, Kopfweg
			06JUN2011	YES	6:30	YES	17:50	Kopfweg, Kopfstechen, Unwohl - Magenschmerzen
			07JUN2011	YES	6:50	YES	18:00	Unwohl - Magenschmerzen, Kopfstechen, Husten
			08JUN2011	YES	7:10	YES	19:10	Unwohl - Magenschmerzen, Kopfstechen, Husten, Arzt-Besuch Dr. Krall
			09JUN2011	YES	6:50	YES	17:30	Unwohl - Magenschmerzen, Husten-Blase-schmerz, Kopfstechen, Hausarzt
			10JUN2011	YES	6:40	YES	18:10	Kopfstechen, Blase-Schmerzen, Kopfweg, 1 Aspirin
			11JUN2011	YES	7:00	YES	17:50	Kopfweg, Ohrenweh, Blasenschmerz
			12JUN2011	YES	8:55	YES	18:00	Kopfstechen "rechts", Ohrenweh "rechts", Müdigkeit
			13JUN2011	YES	7:50	YES	19:00	Kopfstechen, Blasenschmerzen, Tablette nach dem Essen eingenommen
			14JUN2011	YES	7:30	YES	18:30	Kopfstechen, Ohrenschmerzen, Kopfweg, Magenschmerzen, von 10.06.-16.06. Tricef 400 mg 1x1
			15JUN2011	YES	8:10	YES	18:30	Kopfweg, Magenschmerzen, Blasenschmerzen
			16JUN2011			YES	17:50	Kopfstechen, keine Tabletten - Morgens?
			17JUN2011	YES	7:45	YES	18:00	Kopfstechen, Ohrenschmerzen
			18JUN2011	YES	8:10	YES	17:30	Kopfweg, Blasenschmerzen
			19JUN2011	YES	7:10	YES	18:20	Ohrenstechen rechts, Kopfstechen am Hinterkopf
			20JUN2011	YES	7:20	YES	18:00	Kopfstechen
			21JUN2011	YES	6:45	YES	17:30	Kopfstechen, Ohrenschmerzen
			22JUN2011	YES	7:10	YES	17:50	Kopfstechen
			23JUN2011	YES	7:00	YES	17:50	Kopfstechen, Ohrenschmerzen

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	24JUN2011	YES	6:50	YES	17:45	Kopfstechen
			25JUN2011	YES	6:50	YES	17:30	Kopfstechen, Kopfsausen
			26JUN2011	YES	6:30	YES	17:40	Kopfstechen
			27JUN2011	YES	7:05	YES	17:50	Kopfstechen, Ohrenschmerz
			28JUN2011	YES	7:00	YES	17:50	Kopfweh
			29JUN2011	YES	7:10	YES	18:05	Kopfstechen, Kopfsausen
			30JUN2011	YES	7:15	YES	17:30	Kopfstechen, Kopfsausen
			01JUL2011	YES	6:50	YES	17:40	Kopfweh, Ohrensausen
			02JUL2011	YES	7:05	YES	18:00	Kopfweh
			03JUL2011	YES	7:15	YES	18:10	Kopfweh
			04JUL2011	YES	7:20			
			04JUL2011			YES		Untersuchung in der Klinik
			05JUL2011	YES	7:10	YES	18:20	leichtes Kopfweh
			06JUL2011	YES	6:50	YES	17:20	Berg Wanderung Leichtes Kopfweh
			07JUL2011	YES	6:30	YES	17:30	Kopfstechen
			08JUL2011	YES	7:00	YES	18:10	Leichtes Kopfstechen
			09JUL2011	YES	7:20	YES	18:30	Leichtes Kopfstechen
			10JUL2011	YES	7:50	YES	18:50	Kopfstechen
			11JUL2011	YES	7:10	YES	18:15	Kopfstechen
			12JUL2011	YES	7:00	YES	19:00	Kopfweh "Föhnig"
			13JUL2011	YES	6:50	YES	18:00	Leichtes Kopfstechen "Föhnig"
			14JUL2011	YES	7:05	YES	18:10	Kopfstechen
			15JUL2011	YES	6:45	YES	17:40	Kopfweh
			16JUL2011	YES	8:10	YES	18:05	Leichtes Kopfstechen

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	17JUL2011	YES	7:10	YES	17:30	Leichtes Kopfstech an der linken Seite
			18JUL2011	YES	7:30	YES	18:00	Bergwandern "Stahelberg"
			19JUL2011	YES	6:45	YES	18:10	Kopfstechen am Hinterkopf
			20JUL2011	YES	7:10	YES	18:20	Kopfstechen
			21JUL2011	YES	7:00	YES	18:10	Kopfstechen
			22JUL2011	YES	7:20	YES	18:10	Starkes Kopfstech Kopfweh am Abend
			23JUL2011	YES	7:10		19:00	Kopfweh
			24JUL2011	YES	6:45	YES	18:30	Kopfweh Übelkeit
			25JUL2011	YES	7:00	YES	18:15	starkes Kopfstechen am Hinterkopf Kopfweh
			26JUL2011	YES	6:40	YES	18:10	starkes Kopfstechen Kopfweh "morgens"
			27JUL2011	YES	6:50	YES	18:40	starkes Kopfstechen + Kopfweh den ganzen Tag
			28JUL2011	YES	6:50	YES	17:30	Kopfweh
			29JUL2011	YES	7:10	YES	17:50	Kopfstechen Kopfrieseln den Tag
			30JUL2011	YES	7:10	YES	18:00	Kopfstechen den ganzen Tag
			01AUG2011	YES	8:00	YES	18:00	Kopfstechen am Hinterkopf
			02AUG2011	YES	6:50	YES	17:20	Kopfstechen sehr Müde den ganzen Tag
			03AUG2011	YES	6:45	YES	17:50	Kopfstechen am Hinterkopf sehr müde
			04AUG2011	YES	6:30	YES	18:10	Kopfweh
			05AUG2011	YES	6:45	YES	18:00	Kopfstechen
			06AUG2011	YES	7:10	YES	17:20	Kopfstechen
			07AUG2011	YES	6:50	YES	17:50	Kopfstechen
			08AUG2011	YES	6:50	YES	18:05	Kopfstechen Unwohl
			09AUG2011	YES	7:00	YES	18:10	Kein Kopfweh
			10AUG2011	YES	7:20	YES	18:10	Sehr starkes Kopfstechen

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	11AUG2011	YES	6:45	YES	17:20	Kopfstechen
			12AUG2011	YES	7:10	YES	17:20	Kopfweh Kopfstechen
			13AUG2011	YES	7:30	YES	18:00	starkes Kopfstechen
			14AUG2011	YES	7:20	YES	18:10	Kopfstechen
			15AUG2011	YES	7:30	YES	18:20	sehr starkes Kopfstechen
			16AUG2011	YES	6:55	YES	17:45	Kopfstechen sehr stark Unwohl
			17AUG2011	YES	6:50	YES	18:10	sehr starkes Kopfstechen Unwohl gefühl
			18AUG2011	YES	7:00	YES	18:00	sehr starkes Kopfstechen Wander
			19AUG2011	YES	6:50	YES	17:30	starkes Kopfstechen den ganzen Tag Kopfweh
			20AUG2011	YES	7:00	YES	18:20	Kopfstechen
			21AUG2011	YES	7:00	YES	18:00	starkes Kopfstechen unwohl
			22AUG2011	YES	6:40	YES	18:50	Kopfweh Wander
			23AUG2011	YES	7:00	YES	17:20	Kopfweh
			24AUG2011	YES	6:20	YES	18:10	Kopfstechen sehr stark
			25AUG2011	YES	7:40	YES	18:20	Kopfstechen unwohl
			26AUG2011	YES	7:10	YES	17:50	Kopfstechen
			27AUG2011	YES	7:45	YES	17:50	Kopfstechen Magenschmerzen
			28AUG2011	YES	6:50	YES	18:10	Kopfstechen Magenschmerzen
			29AUG2011	YES	6:55	YES	18:20	Kopfstechen
			30AUG2011	YES	7:20	YES	18:00	starkes Kopfstechen Kreislauf schwächen
			31AUG2011	YES	7:10	YES	17:30	Kopfstechen Sturz beim Gehen Gesichtsverletzung
			01SEP2011	YES	7:00	YES	17:50	Kopfweh Unsicher beim Kochen
			02SEP2011	YES	6:45	YES	17:00	starkes Kopfstechen
			03SEP2011	YES	6:55	YES	18:00	starkes Kopfstechen
			04SEP2011	YES	7:10	YES	17:50	starkes Kopfstechen Bauchweh

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	05SEP2011	YES	7:20	YES	18:10	Kreislauf schwächen Kopfstechen
			06SEP2011	YES	6:45	YES	17:50	Kopfstechen Kreislauf unregelmäßig
			07SEP2011	YES	7:10	YES	18:00	Kopfweh Kreislauf ???
			08SEP2011	YES	7:00		18:00	Kopfstechen Kreislauf Unwohl
			09SEP2011	YES	7:10	YES	18:10	Kopfstechen
			10SEP2011	YES	6:50	YES	17:45	Kopfstechen Kreislaufschwächen
			11SEP2011	YES	7:15	YES	17:40	Kopfweh
			12SEP2011	YES	6:50	YES	18:00	Kopfstechen Kreislauf schwächen
			13SEP2011	YES	7:00	YES	18:15	Kopfstechen
			14SEP2011	YES		YES		Kopfstechen Einschlafgefühle
			15SEP2011	YES	7:30	YES	18:00	Druck am Kopf
			16SEP2011	YES	7:10	YES	18:00	Kopfstechen bei Wanderung
			17SEP2011	YES	6:45	YES	17:50	Kopfstechen
			18SEP2011	YES	7:20	YES	17:40	Kopfstechen sehr stark
			19SEP2011	YES	6:45	YES	17:50	Kopfstechen Magenschmerzen
			20SEP2011	YES	6:50	YES	18:00	Kopfweh Magenschmerzen
			21SEP2011	YES	7:20	YES	17:30	Kopfweh Magenschmerzen
			22SEP2011	YES	7:30	YES	17:50	Kopfstechen Magenschmerzen
			23SEP2011	YES	6:30	YES	17:20	Kopfstechen
			24SEP2011	YES	6:50	YES	18:00	Kopfstechen
			25SEP2011	YES	6:50	YES	17:20	Kopfstechen
			26SEP2011	YES	7:00	YES	18:10	Kopfstechen
			27SEP2011	YES	7:05	YES	17:50	Kopfstechen
			28SEP2011	YES	7:00	YES	17:40	Kopfweh
			29SEP2011	YES	6:40	YES	17:50	Kopfweh

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	30SEP2011	YES	6:50	YES	17:40	Leichtes Kopfstechen
			01OCT2011	YES	7:00	YES	17:50	Leichtes Kopfstechen
			02OCT2011	YES	7:00		18:10	Kopfweh
			03OCT2011	YES	7:20	YES	17:30	Kopfweh Gliederschmerzen
			04OCT2011	YES	7:10	YES	17:50	Kopfweh Gliederschmerzen
			05OCT2011	YES	7:05	YES	18:00	Kopfstechen
			06OCT2011	YES	7:00	YES	17:50	Kopfstechen
			07OCT2011	YES	6:50	YES	18:10	Kopfstechen Lähmungs erscheinung linke Gesicht hälfte 3 h in der Früh
			08OCT2011	YES	7:10	YES	18:00	Kopfstechen Kopfweh
			09OCT2011	YES	7:20	YES	17:30	Kopfstechen Kurzzeit Gedächtnis ??
			10OCT2011	YES	7:05	YES	18:10	Kopfstechen
			11OCT2011	YES		YES		Gliederschmerzen Unwohl
			12OCT2011	YES	7:05	YES	18:00	Leichtes Kopfweh
			13OCT2011	YES	7:05	YES	18:10	Kopfstechen
			14OCT2011	YES	6:55	YES	17:40	Kopfstechen Glieder Schmerzen
			15OCT2011	YES	6:50	YES	19:10	Kopfstechen
			16OCT2011	YES	7:00	YES	18:05	Kopfstechen
			17OCT2011	YES	7:00	YES	17:45	Starkes Kopfstechen
			18OCT2011	YES	6:50	YES	17:30	Kopfstechen Magenschmerzen
			19OCT2011	YES	7:10	YES	17:45	Kopfstechen
			20OCT2011	YES	7:00	YES	17:30	Kopfstechen
			21OCT2011	YES	6:50	YES	17:30	Kopfstechen Gliederschmerzen
			22OCT2011	YES	6:45	YES	17:10	Kopfstechen
			23OCT2011	YES	6:45	YES	17:30	Kopfstechen

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	050	21	24OCT2011	YES	6:15			Tabletten bis 2.11. eingeordnet
	052	21	14NOV2000	YES	8:00	YES	18:00	
			10AUG2001	YES	7:30	YES	18:00	
			09JAN2010	YES	8:00	YES	17:00	
			10OCT2010	YES	8:00	YES	17:00	
			29OCT2010	YES	7:00	YES	17:00	
			30OCT2010	YES	8:00	YES	17:00	
			31OCT2010	YES	8:00	YES	17:00	
			01NOV2010	YES	7:00	YES	18:00	Kopfschmerzen
			02NOV2010	YES	7:00	YES	17:00	
			03NOV2010	YES	7:00	YES	17:00	
			04NOV2010	YES	7:00	YES	17:00	
			05NOV2010	YES	8:00	YES	18:00	
			06NOV2010	YES	8:00	YES	18:00	
			07NOV2010	YES	8:00	YES	18:00	
			08NOV2010	YES	8:00	YES	17:00	
			09NOV2010	YES	8:00	YES	18:00	
			11NOV2010	YES	8:00	YES	18:00	
			12NOV2010	YES	8:00	YES	19:00	
			13NOV2010	YES	8:00	YES	17:00	
			15NOV2010	YES	8:00	YES	17:00	
			16NOV2010	YES	8:00	YES	18:00	
			17NOV2010	YES	8:00	YES	17:00	
			18NOV2010	YES	8:00	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	19NOV2010	YES	8:00	YES	17:00	
			20NOV2010	YES	8:00	YES	18:00	
			21NOV2010	YES	8:00	YES	17:00	
			22NOV2010	YES	8:00	YES	17:00	
			23NOV2010	YES	7:00			
			24NOV2010	YES	8:00	YES	17:00	
			25NOV2010	YES	8:00	YES	17:30	
			26NOV2010	YES	8:00	YES	17:30	
			27NOV2010	YES	8:00	YES	18:00	
			28NOV2010	YES	8:00	YES	17:00	
			29NOV2010	YES	8:00	YES	17:00	
			30NOV2010	YES	8:00	YES	17:30	
			01DEC2010	YES	8:00	YES	18:00	
			02DEC2010	YES	7:30	YES	17:00	
			03DEC2010	YES	8:00	YES	17:00	
			04DEC2010	YES	7:30	YES	17:00	
			05DEC2010	YES	8:00	YES	18:00	
			06DEC2010	YES	8:00	YES	18:00	
			07DEC2010	YES	7:30	YES	18:00	
			08DEC2010	YES	8:00	YES	17:30	
			09DEC2010	YES	8:00	YES	17:00	
			10DEC2010	YES	8:00	YES	18:00	
			11DEC2010	YES	8:00	YES	18:00	
			12DEC2010	YES	8:00	YES	17:30	
			13DEC2010	YES	8:00	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	14DEC2010	YES	8:00	YES	17:00	
			15DEC2010	YES	7:30	YES	18:00	
			16DEC2010	YES	7:30	YES	18:00	
			17DEC2010	YES	8:00	YES	17:00	
			18DEC2010	YES	8:00	YES	17:30	
			19DEC2010	YES	7:30	YES	18:00	
			20DEC2010	YES	8:00	YES	18:00	
			21DEC2010	YES	7:30	YES	17:00	
			22DEC2010	YES	7:30	YES	17:00	
			23DEC2010	YES	7:30	YES	17:30	
			24DEC2010	YES	8:00	YES	18:00	
			25DEC2010	YES	7:30	YES	18:00	
			26DEC2010	YES	7:30	YES	17:00	
			27DEC2010	YES	7:30	YES	17:00	
			28DEC2010	YES	8:00	YES	17:00	
			29DEC2010	YES	7:30	YES	17:00	
			30DEC2010	YES	8:00	YES	17:30	
			31DEC2010	YES	7:30	YES	18:00	
			01JAN2011	YES	7:30	YES	17:30	
			02JAN2011		8:00	YES	17:30	
			04JAN2011	YES	7:30	YES	17:00	
			05JAN2011	YES	7:30	YES	17:00	
			06JAN2011	YES	8:00	YES	18:00	
			07JAN2011	YES	8:00	YES	18:00	
			08JAN2011	YES	7:30	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	10JAN2011	YES	7:30	YES	17:00	
			11JAN2011	YES	7:30	YES	17:00	
			12JAN2011	YES	8:00	YES	17:00	
			13JAN2011	YES	8:00	YES	17:30	
			14JAN2011	YES	7:30	YES	17:30	
			15JAN2011	YES	8:00	YES	18:00	
			16JAN2011	YES	7:30	YES	17:30	
			17JAN2011	YES	6:00			
			18JAN2011	YES	7:15	YES	17:30	
			19JAN2011	YES	7:30	YES	17:00	
			20JAN2011	YES	7:30	YES	17:15	
			21JAN2011	YES	7:00	YES	17:15	
			22JAN2011	YES	7:30	YES	17:30	
			23JAN2011	YES	7:15	YES	17:00	
			24JAN2011	YES	7:30	YES	17:15	
			25JAN2011	YES	7:15	YES	18:00	
			26JAN2011	YES	7:15	YES	17:30	
			27JAN2011	YES	7:00	YES	17:00	
			28JAN2011	YES	7:30	YES	17:15	
			29JAN2011	YES	7:30	YES	17:30	
			30JAN2011	YES	7:15	YES	18:00	
			31JAN2011	YES	7:30	YES	18:15	
			01FEB2011	YES	7:30	YES	17:30	
			02FEB2011	YES	7:15	YES	17:15	
			03FEB2011	YES	7:15	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	04FEB2011	YES	7:30	YES	18:00	
			05FEB2011	YES	7:15	YES	17:00	
			06FEB2011	YES	7:15	YES	17:30	
			07FEB2011	YES	7:30	YES	7:15	
			08FEB2011	YES	7:15	YES	17:30	
			09FEB2011	YES	7:30	YES	17:00	
			10FEB2011	YES	7:15	YES	17:30	
			11FEB2011	YES	7:15	YES	17:30	
			12FEB2011	YES	7:15	YES	17:30	
			13FEB2011	YES	7:15	YES	17:30	
			14FEB2011	YES	7:30	YES	18:30	
			15FEB2011	YES	7:15	YES	17:15	
			16FEB2011	YES	7:30	YES	17:15	
			17FEB2011	YES	7:30	YES	18:00	
			18FEB2011	YES	7:15	YES	18:30	
			19FEB2011	YES	7:30	YES	17:30	
			20FEB2011	YES	7:15	YES	17:30	
			21FEB2011	YES	7:15	YES	17:30	
			22FEB2011	YES	7:30	YES	18:00	
			23FEB2011	YES	7:15	YES	18:00	
			24FEB2011	YES	7:15	YES	18:00	
			25FEB2011	YES	7:15	YES	17:30	
			26FEB2011	YES	7:30	YES	17:30	
			27FEB2011	YES	7:15	YES	18:00	
			28FEB2011	YES	7:15	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	01MAR2011	YES	7:30	YES	17:30	
			02MAR2011	YES	7:30	YES	18:00	
			03MAR2011	YES	7:15	YES	17:15	
			04MAR2011	YES	7:30	YES	18:00	
			05MAR2011	YES	7:15	YES	17:30	
			06MAR2011	YES	7:15	YES	17:30	
			07MAR2011	YES	7:15	YES	18:30	
			08MAR2011	YES	7:15	YES	17:30	
			09MAR2011	YES	7:15	YES	17:00	
			10MAR2011	YES	7:30	YES	17:30	
			11MAR2011	YES	7:15	YES	18:00	
			12MAR2011	YES	7:15	YES	17:30	
			13MAR2011	YES	7:15	YES	18:00	
			14MAR2011	YES	7:15	YES	17:30	
			15MAR2011	YES	7:15	YES	19:00	
			16MAR2011	YES	7:15	YES	18:30	
			17MAR2011	YES	7:30	YES	17:30	
			18MAR2011	YES	7:15	YES	18:00	
			19MAR2011	YES	7:15	YES	17:30	
			20MAR2011	YES	7:15	YES	17:30	
			21MAR2011	YES	7:15	YES	17:30	
			22MAR2011	YES	7:30	YES	18:00	
			23MAR2011	YES	7:15	YES	18:00	
			24MAR2011	YES	7:15	YES	17:30	
			25MAR2011	YES	7:15	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	26MAR2011	YES	7:15	YES	18:00	
			27MAR2011	YES	7:15	YES	17:30	
			28MAR2011	YES	7:15	YES	17:30	
			29MAR2011	YES	7:15	YES	17:30	
			30MAR2011	YES	7:30	YES	18:00	
			31MAR2011	YES	7:15	YES	18:00	
			01APR2011	YES	7:15	YES	17:30	
			02APR2011	YES	7:15	YES	17:30	
			03APR2011	YES	7:30	YES	18:00	
			04APR2011	YES	7:15	YES	18:00	
			05APR2011	YES	7:15	YES	17:30	
			06APR2011	YES	7:15	YES	18:30	
			07APR2011	YES	7:15	YES	17:00	
			08APR2011	YES	7:15		17:30	
			09APR2011	YES	7:15	YES	18:00	
			10APR2011	YES	7:15	YES	18:00	
			11APR2011	YES	6:30			
			25MAY2011	YES	8:00	YES	18:00	
			26MAY2011	YES	7:00	YES	17:30	
			27MAY2011	YES	7:00	YES	18:00	
			28MAY2011	YES	7:30	YES	18:00	
			29MAY2011	YES	7:00	YES	18:00	
			30MAY2011	YES	7:30	YES	17:30	
			31MAY2011	YES	7:00	YES	17:30	
			01JUN2011	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	02JUN2011	YES	7:00	YES	18:00	
			03JUN2011	YES	7:00	YES	17:00	
			04JUN2011	YES	7:00	YES	17:30	
			05JUN2011	YES	7:30	YES	17:30	
			06JUN2011	YES	7:00	YES	20:00	
			07JUN2011	YES	7:00	YES	18:00	
			08JUN2011	YES	7:00	YES	18:00	
			09JUN2011	YES	7:00	YES	17:00	
			10JUN2011	YES	7:30	YES	18:00	
			11JUN2011	YES	7:30	YES	18:00	
			12JUN2011	YES	7:00	YES	19:00	
			13JUN2011	YES	7:00	YES	18:00	
			14JUN2011	YES	7:00	YES	18:00	
			15JUN2011	YES	7:30	YES	17:00	
			16JUN2011	YES	7:30	YES	17:00	
			17JUN2011	YES	7:30	YES	17:30	
			18JUN2011	YES	7:00	YES	17:30	
			19JUN2011	YES	7:00	YES	18:00	
			20JUN2011	YES	7:00	YES	18:00	
			21JUN2011	YES	7:00	YES	17:00	
			22JUN2011	YES	7:30	YES	17:30	
			23JUN2011	YES	7:30	YES	17:00	
			24JUN2011	YES	7:00	YES	17:00	
			25JUN2011	YES	7:00	YES	18:00	
			26JUN2011	YES	7:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	27JUN2011	YES	7:00	YES	17:00	
			28JUN2011	YES	7:00	YES	17:30	
			29JUN2011	YES	7:00	YES	17:00	
			30JUN2011	YES	7:00	YES	17:30	
			01JUL2011	YES	7:00	YES	17:30	
			02JUL2011	YES	7:30	YES	18:00	
			03JUL2011	YES	7:00	YES	20:00	
			04JUL2011	YES	6:00			
			04JUL2011	YES	8:00	YES	17:00	
			05JUL2011	YES	7:30	YES	17:30	
			06JUL2011	YES	7:30	YES	17:00	
			07JUL2011	YES	8:00	YES	18:00	
			08JUL2011	YES	8:00	YES	18:00	
			09JUL2011	YES	7:00	YES	17:30	
			10JUL2011	YES	7:00	YES	17:30	
			11JUL2011	YES	7:30	YES	17:00	
			12JUL2011	YES	7:30	YES	18:00	
			13JUL2011	YES	7:30	YES	17:30	
			14JUL2011	YES	7:30	YES	17:30	
			15JUL2011	YES	7:30	YES	17:00	
			16JUL2011	YES	7:00	YES	17:30	
			17JUL2011	YES	8:00	YES	17:00	
			18JUL2011	YES	7:30	YES	18:00	
			19JUL2011	YES	7:30	YES	18:00	
			20JUL2011	YES	7:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	21JUL2011	YES	7:30	YES	18:00	
			22JUL2011	YES	7:30	YES	18:00	
			23JUL2011	YES	7:30	YES	17:30	
			24JUL2011	YES	7:00	YES	17:30	
			25JUL2011	YES	8:00	YES	18:00	
			26JUL2011	YES	8:00	YES	19:00	
			27JUL2011	YES	7:30	YES	17:00	
			28JUL2011	YES	7:30	YES	18:00	
			29JUL2011	YES	7:00	YES	18:00	
			30JUL2011	YES	8:00	YES	17:30	
			31JUL2011	YES	7:30	YES	18:00	
			01AUG2011	YES	8:00	YES	18:00	
			02AUG2011	YES	7:30	YES	17:00	
			03AUG2011	YES	7:30	YES	17:00	
			04AUG2011	YES	7:30	YES	17:30	
			05AUG2011	YES	7:30	YES	17:00	
			06AUG2011	YES	7:00	YES	17:00	
			07AUG2011	YES	7:00	YES	17:30	
			08AUG2011	YES	8:00	YES	18:00	
			09AUG2011	YES	7:30	YES	18:00	
			11AUG2011	YES	8:00	YES	18:00	
			12AUG2011	YES	8:00	YES	18:30	
			13AUG2011	YES	7:00	YES	17:30	
			14AUG2011	YES	7:30	YES	17:00	
			15AUG2011	YES	7:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	16AUG2011	YES	7:30	YES	17:30	
			17AUG2011	YES	8:00	YES	18:00	
			18AUG2011	YES	7:30	YES	18:00	
			19AUG2011	YES	8:00	YES	18:30	
			20AUG2011	YES	8:00	YES	17:30	
			21AUG2011	YES	7:00	YES	17:30	
			22AUG2011	YES	7:00	YES	18:00	
			23AUG2011	YES	7:30	YES	18:00	
			24AUG2011	YES	8:00	YES	18:00	
			25AUG2011	YES	8:00	YES	17:00	
			26AUG2011	YES	7:00	YES	17:00	
			27AUG2011	YES	7:30	YES	18:00	
			28AUG2011	YES	7:00	YES	18:30	
			29AUG2011	YES	7:00	YES	18:00	
			30AUG2011	YES	8:00	YES	17:30	
			31AUG2011	YES	8:00	YES	17:30	
			01SEP2011	YES	7:30	YES	18:00	
			02SEP2011	YES	7:30	YES	18:00	
			03SEP2011	YES	7:00	YES	17:30	
			04SEP2011	YES	7:00	YES	20:00	
			05SEP2011	YES	7:30	YES	18:00	
			06SEP2011	YES	8:00	YES	17:00	
			07SEP2011	YES	8:00	YES	17:00	
			08SEP2011	YES	7:00	YES	17:00	
			09SEP2011	YES	7:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	10SEP2011	YES	8:00	YES	20:00	
			11SEP2011	YES	8:00	YES	18:00	
			12SEP2011	YES	8:00	YES	17:00	
			13SEP2011	YES	7:00	YES	17:00	
			14SEP2011	YES	7:30	YES	18:00	
			15SEP2011	YES	8:00	YES	18:30	
			16SEP2011	YES	8:00	YES	17:30	
			17SEP2011	YES	7:00	YES	17:30	
			18SEP2011	YES	7:00	YES	17:00	
			19SEP2011	YES	7:30	YES	18:00	
			20SEP2011	YES	8:00	YES	17:30	
			21SEP2011	YES	8:00	YES	17:30	
			22SEP2011	YES	8:00	YES	18:00	
			23SEP2011	YES	7:30	YES	18:00	
			24SEP2011	YES	7:30	YES	18:30	
			25SEP2011	YES	8:00	YES	17:30	
			26SEP2011	YES	8:00	YES	17:30	
			27SEP2011	YES	7:00	YES	17:00	
			28SEP2011	YES	7:30	YES	18:00	
			29SEP2011	YES	7:30	YES	18:00	
			30SEP2011	YES	7:00	YES	17:00	
			01OCT2011	YES	7:00	YES	17:00	
			02OCT2011	YES	7:00	YES	18:00	
			03OCT2011	YES	7:30	YES	18:30	
			04OCT2011	YES	7:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	052	21	05OCT2011	YES	8:00	YES	17:00	
			06OCT2011	YES	8:00	YES	17:00	
			07OCT2011	YES	7:30	YES	17:30	
			08OCT2011	YES	7:30	YES	17:30	
			09OCT2011	YES	8:00	YES	18:00	
			10OCT2011	YES	8:00	YES	18:00	
			11OCT2011	YES	7:30	YES	18:00	
			12OCT2011	YES	7:30	YES	17:00	
			13OCT2011	YES	8:00	YES	17:30	
			14OCT2011	YES	8:00	YES	17:00	
			15OCT2011	YES	7:00	YES	18:00	
			16OCT2011	YES	7:00	YES	18:00	
			17OCT2011	YES	7:30	YES	19:00	
			18OCT2011	YES	7:30	YES	17:00	
			19OCT2011	YES	8:00	YES	18:00	
			20OCT2011	YES	7:30	YES	18:00	
			21OCT2011	YES	7:30	YES	17:00	
			22OCT2011	YES	7:30	YES	17:00	
			23OCT2011	YES	7:00	YES	7:30	
			24OCT2011	YES	7:00			
	057	1	20AUG2010	YES	6:30	YES	18:30	
			21AUG2010	YES	7:30	YES	18:00	
			22AUG2010	YES	7:00	YES	18:30	
			23AUG2010	YES	7:20	YES	18:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	057	1	24AUG2010	YES	6:45	YES	17:45	
			25AUG2010	YES	7:00	YES	19:15	
			26AUG2010	YES	6:30	YES	18:15	
			27AUG2010	YES	6:30	YES	18:45	
			28AUG2010	YES	6:45	YES	17:30	
			29AUG2010	YES	7:00	YES	17:30	
			30AUG2010	YES	7:30	YES	17:30	
			31AUG2010	YES	6:45	YES	18:00	
			01SEP2010	YES	7:15	YES	18:30	
			02SEP2010	YES	6:30	YES	17:45	
			03SEP2010	YES	6:30	YES	17:30	
			04SEP2010	YES	6:30	YES	17:30	
			05SEP2010	YES	7:00	YES	17:30	
			06SEP2010	YES	6:45	YES	17:30	
			07SEP2010	YES	7:45	YES	17:30	
			08SEP2010	YES	7:45	YES	17:30	
			09SEP2010	YES	7:00	YES	17:45	
			10SEP2010	YES	7:00	YES	17:30	
			11SEP2010	YES	7:00	YES	18:15	
			12SEP2010	YES	7:00	YES	17:30	
			13SEP2010	YES	6:45	YES	17:00	
			14SEP2010	YES	7:15	YES	17:30	
			15SEP2010	YES	7:15	YES	17:45	
			16SEP2010	YES	7:30	YES	17:30	
			17SEP2010	YES	7:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	057	1	18SEP2010	YES	7:00	YES	17:30	
			19SEP2010	YES	7:30	YES	18:00	
			20SEP2010	YES	7:00			
			21SEP2010	YES	7:00	YES	17:30	
			22SEP2010	YES	7:30	YES	17:30	
			23SEP2010	YES	7:30	YES	17:15	
			24SEP2010	YES	7:15	YES	17:30	
			25SEP2010	YES	7:15	YES	17:30	
			26SEP2010	YES	7:15	YES	17:45	
			27SEP2010	YES	7:15	YES	17:15	
			28SEP2010	YES	7:00	YES	17:30	
			29SEP2010	YES	7:00	YES	17:00	
			30SEP2010	YES	6:45	YES	17:15	
			01OCT2010	YES	6:45	YES	17:00	
			02OCT2010	YES	7:00	YES	17:00	
			03OCT2010	YES	7:00	YES	17:00	
			04OCT2010	YES	7:00	YES	16:45	
			05OCT2010	YES	7:00	YES	17:15	
			06OCT2010	YES	7:00	YES	17:30	
			07OCT2010	YES	7:00	YES	17:15	
			08OCT2010	YES	7:00	YES	17:00	
			09OCT2010	YES	7:00	YES	17:00	
			10OCT2010	YES	7:10	YES	17:10	
			11OCT2010	YES	7:10	YES	17:15	
			12OCT2010	YES	7:15	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	057	1	13OCT2010	YES	7:00	YES	17:00	
			14OCT2010	YES	7:00	YES	16:45	
			15OCT2010	YES	7:00	YES	16:45	
			16OCT2010	YES	7:00	YES	17:00	
			17OCT2010	YES	7:30	YES	17:30	
			18OCT2010	YES	7:00	YES	16:45	
			19OCT2010	YES	7:00	YES	17:00	
			20OCT2010	YES	7:15	YES	16:45	
			21OCT2010	YES	7:00	YES	16:45	
			22OCT2010	YES	7:00	YES	17:00	
			23OCT2010	YES	7:10	YES	17:00	
			24OCT2010	YES	6:45	YES	17:10	
			25OCT2010	YES	7:00	YES	17:00	
			26OCT2010	YES	7:30	YES	18:00	
			27OCT2010	YES	7:15	YES	17:00	
			28OCT2010	YES	7:15	YES	17:10	
			29OCT2010	YES	7:00	YES	17:00	
			30OCT2010	YES	7:00	YES	17:00	
			31OCT2010	YES	7:15	YES	17:15	
			01NOV2010	YES	7:00	YES	17:15	
			02NOV2010	YES	7:00	YES	16:45	
			03NOV2010	YES	7:00	YES	16:45	
			04NOV2010	YES	7:10	YES	16:45	
			05NOV2010	YES	7:10	YES	16:45	
			06NOV2010	YES	7:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	057	1	07NOV2010	YES	7:00	YES	17:15	
			08NOV2010	YES	7:10			
			09NOV2010	YES	7:00	YES	16:45	
			10NOV2010	YES	7:00	YES	17:15	
			11NOV2010	YES	7:10	YES	17:15	
			12NOV2010	YES	7:15	YES	17:00	
			13NOV2010	YES	7:15	YES	17:00	
			14NOV2010	YES	7:00	YES	16:45	
			15NOV2010	YES	7:10	YES	17:00	
			16NOV2010	YES	7:00	YES	17:00	
			17NOV2010	YES	7:00	YES	17:15	
			18NOV2010	YES	6:45	YES	17:00	
			19NOV2010	YES	7:00	YES	17:10	
			20NOV2010	YES	7:00	YES	17:00	
			21NOV2010	YES	7:00	YES	16:45	
			22NOV2010	YES	7:00	YES	16:45	
			23NOV2010	YES	6:10	YES	16:45	
			24NOV2010	YES	7:00	YES	17:00	
			25NOV2010	YES	7:10	YES	17:00	
			26NOV2010	YES	7:15	YES	16:45	
			27NOV2010	YES	7:00	YES	17:00	
			28NOV2010	YES	7:10	YES	17:00	
			29NOV2010	YES	7:15	YES	16:30	
			30NOV2010	YES	7:15	YES	16:30	
			01DEC2010	YES	7:15	YES	17:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	057	1	02DEC2010	YES	7:10	YES	16:45	
			03DEC2010	YES	7:10	YES	16:45	
			04DEC2010	YES	7:00	YES	16:45	
			05DEC2010	YES	7:15	YES	16:45	
			06DEC2010	YES	7:00	YES	17:30	
			07DEC2010	YES	7:00	YES	16:45	
			08DEC2010	YES	7:00	YES	16:45	
			09DEC2010	YES	7:00	YES	16:30	
			10DEC2010	YES	7:00	YES	16:45	
			11DEC2010	YES	7:10	YES	16:45	
			12DEC2010	YES	7:15	YES	16:45	
			13DEC2010	YES	7:15	YES	16:45	
			14DEC2010	YES	7:00	YES	17:00	
			15DEC2010	YES	7:00	YES	16:45	
			16DEC2010	YES	7:00	YES	17:00	
			17DEC2010	YES	7:00	YES	17:30	
			18DEC2010	YES	7:30	YES	17:45	
			19DEC2010	YES	7:15	YES	17:15	
			20DEC2010	YES	7:00	YES	16:45	
			21DEC2010	YES	7:00	YES	16:45	
			22DEC2010	YES	7:00	YES	16:45	
			23DEC2010	YES	7:00	YES	17:00	
			24DEC2010	YES	7:00	YES	16:30	
			25DEC2010	YES	7:30	YES	17:30	
			26DEC2010	YES	7:15	YES	17:15	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	057	1	27DEC2010	YES	7:15	YES	17:30	
			28DEC2010	YES	7:45	YES	16:45	
			29DEC2010	YES	7:15	YES	17:00	
			30DEC2010	YES	7:15	YES	16:45	
			31DEC2010	YES	7:15	YES	16:45	
			01JAN2011	YES	8:00	YES	17:00	
			02JAN2011	YES	7:30	YES	16:45	
			03JAN2011	YES	7:30	YES	16:45	
			04JAN2011	YES	7:30	YES	17:15	
			05JAN2011	YES	7:30	YES	17:00	
			06JAN2011	YES	7:15	YES	16:30	
			07JAN2011	YES	7:15	YES	17:00	
			08JAN2011	YES	7:15	YES	16:30	
			09JAN2011	YES	7:15	YES	16:30	
			10JAN2011	YES	7:00	YES	16:30	
			11JAN2011	YES	7:15	YES	16:45	
			12JAN2011	YES	7:15	YES	16:45	
			13JAN2011	YES	7:15	YES	16:45	
			14JAN2011	YES	7:15	YES	17:00	
			15JAN2011	YES	7:00	YES	16:45	
			16JAN2011	YES	7:15	YES	16:30	
			17JAN2011	YES	7:15	YES	16:30	
			18JAN2011	YES	7:15	YES	16:45	
			19JAN2011	YES	7:00	YES	16:45	
			20JAN2011	YES	7:00	YES	16:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	057	1	21JAN2011	YES	7:10	YES	16:45	
			22JAN2011	YES	7:00	YES	16:45	
			23JAN2011	YES	7:15	YES	17:00	
			24JAN2011	YES	7:15	YES	17:15	
			25JAN2011	YES	7:15	YES	17:30	
			26JAN2011	YES	7:15	YES	17:30	
			27JAN2011	YES	7:30	YES	17:10	
			28JAN2011	YES	7:15	YES	17:00	
			29JAN2011	YES	7:10	YES	17:15	
			30JAN2011	YES	7:15	YES	17:15	
			31JAN2011	YES	7:00	YES	17:30	
			01FEB2011	YES	7:00	YES	16:45	
			02FEB2011	YES	7:00	YES	16:45	
			03FEB2011	YES	7:00	YES	17:00	
			04FEB2011	YES	6:30			
	066	16	14SEP2010	YES	7:15	YES	18:30	
			15SEP2010	YES	7:15	YES	18:45	
			16SEP2010	YES	7:30	YES	18:45	
			17SEP2010	YES	7:30	YES	19:00	
			18SEP2010	YES	7:30	YES	18:30	
			19SEP2010	YES	7:30	YES	18:30	
			20SEP2010	YES	7:30	YES	18:15	
			21SEP2010	YES	7:30	YES	18:45	
			22SEP2010	YES	7:15	YES	18:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	066	16	23SEP2010	YES	7:15	YES	18:30	
			24SEP2010		7:30	YES	18:45	
			25SEP2010	YES	7:45	YES	18:30	
			26SEP2010	YES	7:30	YES	18:45	
			27SEP2010	YES	7:30	YES	18:30	
			28SEP2010	YES	7:30	YES	18:30	
			29SEP2010	YES	7:30	YES	18:15	
			30SEP2010	YES	7:30	YES	18:30	
			01OCT2010	YES	8:00	YES	18:45	
			02OCT2010	YES	7:45	YES	18:45	
			03OCT2010	YES	7:30	YES	19:00	
			04OCT2010	YES	7:15	YES	18:45	
			05OCT2010	YES	7:30	YES	19:00	
			06OCT2010		7:30			
			06OCT2010	YES	7:30	YES	18:15	
			07OCT2010	YES	7:30	YES	18:30	Spritze Vitamin (8) B12
			08OCT2010	YES	7:40	YES	18:00	
			09OCT2010	YES	7:30	YES	18:30	
			10OCT2010	YES	7:30	YES	18:20	
			11OCT2010	YES	7:30	YES	18:30	
			12OCT2010	YES	7:30	YES	19:00	Uni-Klinik T. neue Tabletten
			13OCT2010	YES	7:30	YES	18:15	Aricept 10 mg tgl. vor Bettruhe Vitamin B12 (9)
			14OCT2010	YES	7:30	YES	18:00	10 mg
			15OCT2010	YES	7:30	YES	18:10	
			16OCT2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	066	16	17OCT2010	YES	7:30	YES	18:30	
			18OCT2010	YES	7:30	YES	18:00	
			19OCT2010	YES	7:30	YES	18:15	
			20OCT2010	YES	7:30	YES	18:15	Vitamin B12 (10)
			21OCT2010	YES	7:30	YES	18:10	
			22OCT2010	YES	7:40	YES	18:10	1/2 Tabl. Zolpidem
			23OCT2010	YES	8:30	YES	18:15	Aricept reduziert auf 5 mg
			24OCT2010	YES	7:45	YES	18:30	gestürzt 1/2 Tabl. Zolpidem Notarzt gerufen
			25OCT2010	YES	7:00	YES	18:20	1/2 Tabl. Zolpidem
			26OCT2010	YES	7:30	YES	18:10	
			27OCT2010	YES	7:25	YES	18:20	Vitamin B12 (11.)
			28OCT2010	YES	7:30	YES	18:30	
			29OCT2010	YES	7:20	YES	18:30	
			30OCT2010	YES	7:30	YES	18:30	
			31OCT2010	YES	7:30	YES	18:30	
			01NOV2010	YES	7:30	YES	18:20	
			02NOV2010	YES	7:30	NO	18:30	2 Zahnwurzeln gezogen, verweigert Tablette, verwirrt
			03NOV2010	YES	7:20	YES	18:20	Sehr verwirrt, Vit. B12 (12.), desorientiert, Hausarzt vorgestern
			04NOV2010	YES	7:30	YES	18:25	Verwirrt und ständige Unruhe
			05NOV2010	YES	7:20	NO	18:45	1/2 Tabl. Zolpidem, verweigert Tablette, er ist verwirrt
			06NOV2010	YES	7:50	YES	18:20	
			07NOV2010	YES	7:20	YES	18:25	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	066	16	08NOV2010	YES	7:30	YES	18:30	
			09NOV2010	YES	7:45	YES	18:20	Grippe impfen, Vitamin B12 (13.)
			10NOV2010	YES	7:30	YES	18:15	
			11NOV2010	YES	7:20	YES	18:20	
			12NOV2010	YES	7:30	YES	18:25	Unruhe, verwirrt, aggressiv
			13NOV2010	YES	7:50	YES	18:40	Unruhe, verwirrt, aggressiv
			14NOV2010	YES		YES	18:30	Unruhe, verwirrt, aggressiv
			15NOV2010	YES	7:40	YES	18:35	Unruhe, verwirrt, aggressiv
			16NOV2010	YES	7:35	YES	18:20	Unruhe, verwirrt, aggressiv
			17NOV2010	YES	7:50	YES	18:10	Unruhe, desorientiert, aggressiv, ständig Absicht Wohnung zu verlassen
			18NOV2010	YES		YES	18:45	1x Melperon
			19NOV2010	YES	7:30	YES	18:20	1/2 Melperon
			20NOV2010	YES	7:45	YES	18:20	1/2 Melperon
			21NOV2010	YES	7:30	YES	18:30	1/2 Melperon
			22NOV2010	YES	7:30	YES	18:15	1/2 Melperon
			23NOV2010	YES	7:20	YES	18:20	1/2 Melperon
			24NOV2010	YES	7:30	YES	18:30	1/2 Melperon
			25NOV2010	YES	7:20	YES	18:20	1/2 Melperon
			26NOV2010	YES	7:30	YES	18:20	1/2 Melperon
			27NOV2010	YES	7:30	YES	18:30	1/2 Melperon
			28NOV2010	YES	7:40	YES	18:40	1/2 Melperon
			29NOV2010	YES	7:30	YES	18:20	1/2 Melperon
			30NOV2010	YES	7:00			
			30NOV2010			YES	18:45	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	066	16	01DEC2010	YES	7:45	YES	19:00	
			02DEC2010	YES	8:10	YES	18:30	
			03DEC2010	YES	7:30	YES	18:15	
			04DEC2010	YES	7:45	YES	18:30	
			05DEC2010	YES	7:30	YES	18:45	
			06DEC2010	YES	8:00	YES	18:50	
			07DEC2010	YES	8:20	YES	19:10	
			08DEC2010	YES	8:10	YES	18:10	
			09DEC2010	YES	7:45	YES	18:00	
			10DEC2010	YES	8:20	YES	18:15	
			11DEC2010	YES	8:15	YES	18:30	
			12DEC2010	YES	8:15	YES	18:30	Sehr aggressives Verhalten
			13DEC2010	YES	8:30	YES	18:20	Sehr aggressives Verhalten
			14DEC2010	YES	8:00	YES	18:15	Von Hausärztin an Dr. Bennemann überwiesen
			15DEC2010	YES	8:10	YES	18:30	ab 14.12. Risperidon 1 mg
			16DEC2010	YES	8:00	YES	18:30	1/2 - 1/2
			17DEC2010	YES	7:30	YES	18:20	Unruhig, versucht Tabl. abzuwehren
			18DEC2010	YES	7:45	YES	18:30	Unruhig
			19DEC2010	YES	8:20	NO	18:30	T. abends verweigert, sehr aggressiv
			20DEC2010	YES	8:10	NO	18:45	Abends verweigert, sehr unruhig
			21DEC2010	NO	7:50	NO		Erbrochen, Tabletten abgesetzt
	067	16	19NOV2010	YES	7:30	YES	18:00	Beschwerden (Punkt.), starke Rückenbes.
			20NOV2010	YES	7:30	YES	20:00	Mundtrockenheit, Kopfschmerzen

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	067	16	21NOV2010	YES	8:00	YES	18:30	Mundtrockenheit, starke Kopfschmerzen, Nackensteife
			22NOV2010	YES	7:30	YES	18:00	Sehr starke Kopfschmerzen, Nackensteife + Schmerz!
			23NOV2010	YES	7:45	YES	18:00	Sehr starken Kopfschmerz, Übelkeit
			24NOV2010	YES	9:00	YES	18:00	Immer noch Kopfschm., Übelkeit
			25NOV2010	YES	8:00		18:00	Kopfschmerz aber zu ertragen
			26NOV2010	YES	8:00	YES	18:00	Kopfschmerz
			27NOV2010	YES	8:30	YES	18:00	Kopfschmerz nur noch nach Tabletteneinnahme
			28NOV2010	YES	7:30	NO		Am Abend Tbl. vergessen, waren unterwegs
			29NOV2010	YES	8:00	YES	18:00	Übelkeit + Erbrechen am Morgen und Abend nach der Einnahme
			30NOV2010	YES	7:30	YES	17:30	Nach Einnahme ca. 1 h am Morgen Übelkeit + Erbrechen
			01DEC2010	YES	7:30	YES	18:00	Übelkeit, starke Kopfschmerzen, Nackensteife
			02DEC2010	YES	7:30	YES	18:00	Kopfschmerz, Übelkeit, Erbrechen
			03DEC2010	YES	8:00	YES	18:00	Starke Kopfschm., Übelkeit, Nst.
			04DEC2010	YES	10:00	YES	19:00	Kopfschmerz, Nackensteife, Mundtrockenheit
			05DEC2010	YES	10:00	YES	19:00	Kopfschmerz, Mundtrockenheit
			06DEC2010	YES	7:00	YES	19:00	Kopfschmerz, Mundtrockenheit
			07DEC2010	YES	7:30		18:00	Übelkeit, Kopfschmerz, Erbrechen
			08DEC2010		7:00	YES	18:00	Kopfschmerz
			09DEC2010		7:30	YES	18:00	Kopfschmerz
			10DEC2010	YES	8:00		18:00	Übelkeit
			11DEC2010	YES	7:30	YES	18:00	Kopfschmerz
			12DEC2010	YES	7:30	YES	20:00	Übelkeit 1/2 Std. nach der Einnahme

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	067	16	13DEC2010	YES	7:00	YES	17:30	Übelkeit
			14DEC2010	YES	7:30	YES	17:30	Kopfschmerz
			15DEC2010	YES	7:00	YES	18:00	Kopfschmerz am Morgen
			16DEC2010			YES	18:00	Übelkeit, Kopfschmerz
			17DEC2010	YES		YES		Übelkeit, Kopfschmerz, Erbrechen
			18DEC2010	YES		YES		Übelkeit, Erbrechen, Kopfschmerz
			19DEC2010	YES		YES		Migräneartiger Kopfschmerz + Erbrechen
			20DEC2010	YES		YES		starker Kopfschm., Übelkeit
			21DEC2010	YES		YES		Kopfschmerz, Übelkeit
			22DEC2010	YES		YES		Kopfschmerz
			23DEC2010	YES		YES		Kopfschmerz, Übelkeit
			24DEC2010	YES	7:00	NO		vergessen, Kopfschmerz
			25DEC2010	YES		YES		Kopfschmerz, Übelkeit, Erbrechen
			26DEC2010	YES		YES		Migräneartiger Kopfschmerz
			27DEC2010	YES		YES		Übelkeit, Erbrechen, starker Kopfschmerz
			28DEC2010	YES		YES		starker Kopfschmerz
			29DEC2010	YES		YES		Kopfschmerz, Erbrechen
			30DEC2010	YES		YES		Übelkeit, Erbrechen, Kopfschmerz
			31DEC2010	YES		NO		Kopfschmerz
	071	18	11OCT2010	YES	6:30	YES	17:30	
			10NOV2010	YES	6:30	YES	17:30	
			12NOV2010	YES	6:30	YES	17:30	
			13NOV2010	YES	7:00	YES	18:00	
			14NOV2010	YES	7:30	YES	19:00	leichter Durchfall

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	15NOV2010	YES	6:30	YES	17:30	leichter Durchfall
			16NOV2010	YES	6:30	YES	17:30	leichter Durchfall
			17NOV2010	YES	7:30	YES	18:00	
			18NOV2010	YES	6:30	YES	17:30	
			19NOV2010	YES	6:30	YES	17:30	
			20NOV2010	YES	7:30	YES	18:30	
			21NOV2010	YES	7:30	YES	18:30	
			22NOV2010	YES	7:30	YES	17:30	
			23NOV2010	YES	7:30	YES	17:00	
			24NOV2010	YES	6:30	YES	17:30	
			25NOV2010	YES	6:30	YES	17:30	
			26NOV2010	YES	6:30	YES	17:30	
			27NOV2010	YES	7:30	YES	17:30	
			28NOV2010	YES	6:30	YES	17:30	
			29NOV2010	YES	6:30	YES	17:30	
			30NOV2010	YES	6:30	YES	17:30	
			01DEC2010	YES	6:30	YES	17:30	
			02DEC2010	YES	6:30			
			02DEC2010			YES	17:30	
			03DEC2010	YES	6:30	YES	17:30	
			04DEC2010	YES	7:30	YES	18:00	
			05DEC2010	YES	7:30	YES	18:00	
			06DEC2010	YES	6:30	YES	17:30	
			07DEC2010	YES	6:30	YES	17:30	
			08DEC2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	09DEC2010	YES	6:30	YES	17:30	
			10DEC2010	YES	6:30	YES	17:30	
			11DEC2010	YES	7:30	YES	18:00	
			12DEC2010	YES	7:30	YES	18:00	
			13DEC2010	YES	6:30	YES	18:00	
			14DEC2010	YES	6:30	YES	18:00	
			15DEC2010	YES	7:30	YES	18:00	
			16DEC2010	YES	6:30	YES	18:00	
			17DEC2010	YES	6:30	YES	18:00	
			18DEC2010	YES	7:30	YES	18:00	
			19DEC2010	YES	7:30	YES	17:30	
			20DEC2010	YES	6:30	YES	17:30	
			21DEC2010	YES	6:30	YES	17:30	
			22DEC2010	YES	6:30	YES	18:00	
			23DEC2010	YES	7:00	YES	18:00	
			24DEC2010	YES	7:00	YES	18:00	
			25DEC2010	YES	7:00	YES	18:00	
			26DEC2010	YES	7:00	YES	18:00	
			27DEC2010	YES	7:00	YES	18:00	
			28DEC2010	YES	7:00	YES	18:00	
			29DEC2010	YES	7:00	YES	18:00	
			30DEC2010	YES	7:00	YES	18:00	
			31DEC2010	YES	7:00	YES	18:00	
			01JAN2011	YES	8:00	YES	17:30	
			02JAN2011	YES	7:30			

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	03JAN2011	YES	7:30	YES	17:00	
			04JAN2011	YES	7:30	YES	17:00	
			05JAN2011	YES	7:30	YES	17:30	
			06JAN2011	YES	7:30	YES	17:00	
			07JAN2011	YES	7:30	YES	17:30	
			08JAN2011	YES	7:30	YES	17:30	
			09JAN2011	YES	7:30	YES	17:30	
			10JAN2011	YES	6:30	YES	17:30	
			11JAN2011	YES	6:30	YES	17:30	
			12JAN2011	YES	6:30	YES	17:30	
			13JAN2011	YES	6:30	YES	17:30	
			14JAN2011	YES	6:30	YES	17:30	
			15JAN2011	YES	7:30	YES	18:00	
			16JAN2011	YES	7:30	YES	18:00	
			17JAN2011	YES	6:30	YES	18:00	
			18JAN2011	YES	6:30	YES	18:00	
			19JAN2011	YES	6:30	YES	17:30	
			20JAN2011	YES	6:30	YES	17:30	
			21JAN2011	YES	6:30	YES	17:30	
			22JAN2011	YES	7:30	YES	18:00	
			23JAN2011	YES	7:30	YES	18:00	
			24JAN2011	YES	6:30	YES	17:30	
			25JAN2011	YES	6:30	YES	17:30	
			26JAN2011	YES	6:30	YES	17:30	
			27JAN2011	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	28JAN2011	YES	6:30	YES	17:30	
			29JAN2011	YES	6:30	YES	17:30	
			30JAN2011	YES	7:30	YES	17:30	
			31JAN2011	YES	6:30	YES	17:30	
			01FEB2011	YES	6:30	YES	17:30	
			02FEB2011	YES	6:30	YES	17:30	
			03FEB2011	YES	6:30			
			03FEB2011			YES	17:00	
			04FEB2011	YES	6:30	YES	17:30	
			05FEB2011	YES	7:30	YES	17:30	
			06FEB2011	YES	7:30	YES	17:30	
			07FEB2011	YES	7:00	YES	17:00	
			08FEB2011	YES	7:00	YES	17:00	
			09FEB2011	YES	7:00	YES	17:00	
			10FEB2011	YES	6:30	YES	17:30	
			11FEB2011	YES	6:30	YES	17:30	
			12FEB2011	YES	7:30	YES	17:30	
			13FEB2011	YES	7:30	YES	17:30	
			14FEB2011	YES	6:30	YES	17:30	
			15FEB2011	YES	6:30	YES	17:30	
			16FEB2011	YES	6:30	YES	17:30	
			17FEB2011	YES	6:30	YES	17:30	
			18FEB2011	YES	6:30	YES	17:30	
			19FEB2011	YES	7:30	YES	18:00	
			20FEB2011	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	21FEB2011	YES	6:30	YES	17:00	
			22FEB2011	YES	6:30	YES	17:00	
			23FEB2011	YES	6:30	YES	17:00	
			24FEB2011	YES	6:30	YES	17:00	
			25FEB2011	YES	6:30	YES	17:00	
			26FEB2011	YES	7:00	YES	17:30	
			27FEB2011	YES	7:00	YES	17:30	
			28FEB2011	YES	6:30	YES	17:30	
			01MAR2011	YES	6:30	YES	17:30	
			02MAR2011	YES	6:30	YES	17:30	
			03MAR2011	YES	6:30	YES	17:30	
			04MAR2011	YES	6:30	YES	17:30	
			05MAR2011	YES	7:30	YES	17:30	
			06MAR2011	YES	7:30	YES	17:30	
			07MAR2011	YES	7:00	YES	17:30	
			08MAR2011	YES	7:00	YES	17:30	
			09MAR2011	YES	7:00	YES	17:30	
			10MAR2011	YES	7:00	YES	17:30	
			11MAR2011	YES	6:30	YES	17:30	
			12MAR2011	YES	7:30	YES	18:00	
			13MAR2011	YES	7:30	YES	18:00	
			14MAR2011	YES	6:30	YES	17:30	
			15MAR2011	YES	6:30	YES	17:30	
			16MAR2011	YES	6:30	YES	17:30	
			17MAR2011	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	18MAR2011	YES	6:30	YES	17:30	
			19MAR2011	YES	7:30	YES	18:00	
			20MAR2011	YES	7:30	YES	18:00	
			21MAR2011	YES	6:30	YES	17:30	
			22MAR2011	YES	6:30	YES	18:00	
			23MAR2011	YES	6:30	YES	18:00	
			24MAR2011	YES	6:30	YES	18:00	
			25MAR2011	YES	6:30	YES	18:00	
			26MAR2011	YES	6:30	YES	18:00	
			27MAR2011	YES	7:30	YES	18:00	
			28MAR2011	YES	6:30	YES	18:00	
			29MAR2011	YES	6:30	YES	18:00	
			30MAR2011	YES	6:30	YES	18:00	
			31MAR2011	YES	6:30	YES	18:00	
			01APR2011	YES	6:30	YES	18:00	
			02APR2011	YES	7:30	YES	18:00	
			03APR2011	YES	7:30	YES	18:00	
			04APR2011	YES	6:30	YES	18:00	
			05APR2011	YES	6:30	YES	17:30	
			06APR2011	YES	6:30	YES	17:30	
			07APR2011	YES	6:30	YES	17:30	
			08APR2011	YES	6:30	YES	17:30	
			09APR2011	YES	7:30	YES	18:00	
			10APR2011	YES	7:30	YES	18:00	
			11APR2011	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	12APR2011	YES	6:30	YES	17:30	
			13APR2011	YES	6:30	YES	17:30	
			14APR2011	YES	6:30	YES	17:30	
			15APR2011		6:30	YES	17:30	
			16APR2011	YES	7:30	YES	18:00	
			17APR2011	YES	7:30	YES	18:00	
			18APR2011	YES	7:00	YES	18:00	
			19APR2011	YES	7:00	YES	18:00	
			20APR2011	YES	7:00	YES	18:00	
			21APR2011	YES	7:00	YES	18:00	
			22APR2011	YES	7:30	YES	18:00	
			23APR2011	YES	7:30	YES	18:00	
			24APR2011	YES	7:30	YES	18:00	
			25APR2011	YES	7:30	YES	18:00	
			26APR2011	YES	7:30	YES	18:00	
			27APR2011	YES	7:30	YES	18:00	
			28APR2011	YES	7:30	YES	18:00	
			29APR2011	YES	7:30	YES	18:00	
			30APR2011	YES	7:30	YES	18:00	
			01MAY2011	YES	7:30	YES	18:00	
			02MAY2011	YES	6:30	YES	18:00	
			03MAY2011	YES	6:30	YES	18:00	
			04MAY2011	YES	6:30			
			04MAY2011			YES	17:00	
			05MAY2011	YES	6:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	06MAY2011	YES	6:30	YES	17:00	
			07MAY2011	YES	7:30	YES	17:30	
			08MAY2011	YES	7:30	YES	17:30	
			09MAY2011	YES	6:30	YES	17:00	
			10MAY2011	YES	6:30	YES	17:00	
			11MAY2011	YES	6:30	YES	17:00	
			12MAY2011	YES	6:30	YES	17:00	
			13MAY2011	YES	6:30	YES	17:00	
			14MAY2011	YES	7:30	YES	17:30	
			15MAY2011	YES	7:30	YES	17:30	
			16MAY2011	YES	6:30	YES	17:00	
			17MAY2011	YES	6:30	YES	17:00	
			18MAY2011	YES	6:30	YES	17:00	
			19MAY2011	YES	6:30	YES	17:00	
			20MAY2011	YES	6:30	YES	17:00	
			21MAY2011	YES	7:30	YES	17:30	
			22MAY2011	YES	7:30	YES	17:30	
			23MAY2011	YES	6:30	YES	17:00	
			24MAY2011	YES	6:30	YES	17:00	
			25MAY2011	YES	6:30	YES	17:00	
			26MAY2011	YES	6:30	YES	17:00	
			27MAY2011	YES	6:30	YES	17:00	
			28MAY2011	YES	7:30	YES	17:30	
			29MAY2011	YES	7:30	YES	17:30	
			30MAY2011	YES	6:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	31MAY2011	YES	6:30	YES	17:00	
			01JUN2011	YES	6:30	YES	17:00	
			02JUN2011	YES	7:30	YES	17:30	
			03JUN2011	YES	6:30	YES	17:00	
			04JUN2011	YES	7:30	YES	17:30	
			05JUN2011	YES	7:30	YES	17:30	
			06JUN2011	YES	6:30	YES	17:00	
			07JUN2011	YES	6:30	YES	17:30	
			08JUN2011	YES	6:30	YES	17:30	
			09JUN2011	YES	6:30	YES	17:00	
			10JUN2011	YES	6:30	YES	17:00	
			11JUN2011	YES	7:30	YES	17:30	
			12JUN2011	YES	7:30	YES	17:30	
			13JUN2011	YES	7:30	YES	17:30	
			14JUN2011	YES	7:30	YES	18:00	
			15JUN2011	YES	7:30	YES	18:00	
			16JUN2011	YES	7:30	YES	18:00	
			17JUN2011	YES	7:30	YES	18:00	
			18JUN2011	YES	7:30	YES	18:00	
			19JUN2011	YES	7:30	YES	18:00	
			20JUN2011	YES	7:30	YES	18:00	
			21JUN2011	YES	7:30	YES	18:00	
			22JUN2011	YES	7:30	YES	18:00	
			23JUN2011	YES	7:30	YES	18:00	
			24JUN2011	YES	7:30	YES	18:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	25JUN2011	YES	7:30	YES	18:00	
			26JUN2011	YES	7:00	YES	18:00	
			27JUN2011	YES	6:30	YES	17:30	
			28JUN2011	YES	6:30	YES	17:30	
			29JUN2011	YES	6:30	YES	17:30	
			30JUN2011	YES	6:30	YES	17:30	
			01JUL2011	YES	6:30	YES	17:30	
			02JUL2011	YES	7:00	YES	18:00	
			03JUL2011	YES	7:00	YES	18:00	
			04JUL2011	YES	6:30	YES	17:30	
			05JUL2011	YES	6:30	YES	17:30	
			06JUL2011	YES	6:30	YES	17:30	
			07JUL2011	YES	6:30	YES	17:30	
			08JUL2011	YES	6:30	YES	17:30	
			09JUL2011	YES	7:00	YES	18:00	
			10JUL2011	YES	7:00	YES	18:00	
			11JUL2011	YES	6:30	YES	17:30	
			12JUL2011	YES	6:30	YES	17:30	
			13JUL2011	YES	6:30	YES	17:30	
			14JUL2011	YES	6:30	YES	17:30	
			15JUL2011	YES	7:00	YES	18:00	
			16JUL2011	YES	7:00	YES	18:00	
			17JUL2011	YES	7:00	YES	18:00	
			18JUL2011	YES	7:00	YES	18:00	
			19JUL2011	YES	6:30			

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	19JUL2011			YES	18:00	
			20JUL2011	YES	6:30	YES	18:00	
			21JUL2011	YES	6:30	YES	18:00	
			22JUL2011	YES	6:30	YES	18:00	
			23JUL2011	YES	7:30	YES	18:00	
			24JUL2011	YES	7:30	YES	18:00	
			25JUL2011	YES	6:30	YES	18:00	
			26JUL2011	YES	6:30	YES	18:00	
			27JUL2011	YES	6:30	YES	18:00	
			28JUL2011	YES	6:30	YES	18:00	
			29JUL2011	YES	6:30	YES	18:00	
			30JUL2011	YES	7:30	YES	18:00	
			31JUL2011	YES	7:30	YES	18:00	
			01AUG2011	YES	7:30	YES	18:00	
			02AUG2011	YES	7:30	YES	18:00	
			03AUG2011	YES	7:30	YES	18:00	
			04AUG2011	YES	7:30	YES	18:00	
			05AUG2011	YES	7:30	YES	18:00	
			06AUG2011	YES	7:30	YES	18:00	
			07AUG2011	YES	7:30	YES	18:00	
			08AUG2011	YES	7:00	YES	18:00	
			09AUG2011	YES	7:00	YES	18:00	
			10AUG2011	YES	7:00	YES	18:00	
			11AUG2011	YES	7:30	YES	18:00	
			12AUG2011	YES	7:00	YES	18:00	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	13AUG2011	YES	7:30	YES	18:00	
			14AUG2011	YES	7:30	YES	18:00	
			15AUG2011	YES	7:30	YES	18:00	
			16AUG2011	YES	7:30	YES	18:00	
			17AUG2011	YES	7:30	YES	18:00	
			18AUG2011	YES	7:30	YES	18:00	
			19AUG2011	YES	7:30	YES	18:00	
			20AUG2011	YES	7:30	YES	18:00	
			21AUG2011	YES	7:30	YES	18:00	
			22AUG2011	YES	7:30	YES	18:00	
			23AUG2011	YES	7:30	YES	18:00	
			24AUG2011	YES	7:00	YES	18:00	
			25AUG2011	YES	7:00	YES	18:00	
			26AUG2011	YES	7:00	YES	18:00	
			27AUG2011	YES	7:00	YES	18:00	
			28AUG2011	YES	7:00	YES	18:00	
			29AUG2011	YES	7:00	YES	18:00	
			30AUG2011	YES	7:00	YES	18:00	
			31AUG2011	YES	7:00	YES	18:00	
			01SEP2011	YES	7:00	YES	18:00	
			02SEP2011	YES	7:00	YES	18:00	
			03SEP2011	YES	7:00	YES	18:00	
			04SEP2011	YES	7:00	YES	18:00	
			05SEP2011	YES	7:00	YES	18:00	
			06SEP2011	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	07SEP2011	YES	7:00	YES	18:00	
			08SEP2011	YES	7:00	YES	18:00	
			09SEP2011	YES	7:00	YES	18:00	
			10SEP2011	YES	7:00	YES	18:00	
			11SEP2011	YES	7:00	YES	18:00	
			12SEP2011	YES	7:00	YES	18:00	
			13SEP2011	YES	7:00	YES	18:00	
			14SEP2011	YES	6:30	YES	17:30	
			15SEP2011	YES	6:30	YES	17:30	
			16SEP2011	YES	6:30	YES	17:30	
			17SEP2011	YES	7:00	YES	18:00	
			18SEP2011	YES	7:00	YES	18:00	
			19SEP2011	YES	6:30	YES	17:30	
			20SEP2011	YES	6:30	YES	17:30	
			21SEP2011	YES	6:30	YES	17:30	
			22SEP2011	YES	6:30	YES	17:30	
			23SEP2011	YES	6:30	YES	17:30	
			24SEP2011	YES	7:00	YES	18:00	
			25SEP2011	YES	7:00	YES	18:00	
			26SEP2011	YES	6:30	YES	17:30	
			27SEP2011	YES	6:30	YES	17:30	
			28SEP2011	YES	6:30	YES	17:30	
			29SEP2011	YES	6:30	YES	17:30	
			30SEP2011	YES	6:30	YES	17:30	
			01OCT2011	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	02OCT2011	YES	7:00	YES	18:00	
			03OCT2011	YES	7:00	YES	18:00	
			04OCT2011	YES	6:30	YES	17:30	
			05OCT2011	YES	6:30	YES	18:00	
			06OCT2011	YES	6:30	YES	17:30	
			07OCT2011	YES	6:30	YES	17:30	
			08OCT2011	YES	7:00	YES	18:00	
			09OCT2011	YES	7:00	YES	18:00	
			10OCT2011	YES	6:30	YES	17:30	
			11OCT2011	YES	6:30	YES	17:30	
			12OCT2011	YES	6:30	YES	17:30	
			13OCT2011	YES	6:30	YES	17:30	
			14OCT2011	YES	6:30	YES	17:30	
			15OCT2011	YES	7:00	YES	18:00	
			16OCT2011	YES	7:00	YES	18:00	
			17OCT2011	YES	6:30	YES	17:30	
			18OCT2011	YES	6:30	YES	17:30	
			19OCT2011	YES	6:30	YES	17:30	
			20OCT2011	YES	6:30	YES	17:30	
			21OCT2011	YES	6:30	YES	17:30	
			22OCT2011	YES	7:00	YES	18:00	
			23OCT2011	YES	7:00	YES	18:00	
			24OCT2011	YES	6:30	YES	17:30	
			25OCT2011	YES	6:30	YES	17:30	
			26OCT2011	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	071	18	27OCT2011	YES	6:30	YES	17:30	
			28OCT2011	YES	6:30	YES	17:30	
			29OCT2011	YES	7:00	YES	18:00	
			30OCT2011	YES	7:00	YES	18:00	
			31OCT2011	YES	7:00	YES	18:00	
			01NOV2011	YES	7:00	YES	18:00	
			02NOV2011	YES	7:00	YES	18:00	
			03NOV2011	YES	7:00	YES	18:00	
			04NOV2011	YES	7:00	YES	18:00	
			05NOV2011	YES	6:30	YES	17:30	
			06NOV2011	YES	6:30	YES	17:30	
			07NOV2011	YES	6:30	YES	17:30	
			08NOV2011	YES	6:30	YES	17:30	
			09NOV2011	YES	6:30	YES	17:30	
			10NOV2011	YES	6:30	YES	17:30	
			11NOV2011	YES	6:30	YES	17:30	
			12NOV2011	YES	7:30	YES	18:00	
			13NOV2011	YES	7:30	YES	18:00	
			14NOV2011	YES	6:30	YES	17:30	
			15NOV2011	YES	6:30	YES	17:30	
			16NOV2011	YES	6:30	YES	17:30	
			17NOV2011	YES	6:30			

080

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Meine Frau ist in der Psychiatrie LWL vom
26.2.2011 bis 5.4.2011.

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	080	13	20NOV2010			YES	17:30	nach der Lumbalpunktion keine Beschwerden.
			21NOV2010	YES	7:30	YES	18:30	Keine Beschwerden
			22NOV2010	YES	8:15	YES	19:00	Keine Beschwerden
			23NOV2010	YES	7:15	YES	17:30	Keine Beschwerden
			24NOV2010	YES	7:15	YES	17:30	Auffällig Zunge Schwamm Riße
			25NOV2010	YES	8:00	YES	17:30	Auffällig Zunge Schwamm Riße
			26NOV2010	YES	7:45	YES	17:30	Auffällig Zunge Schwamm Riße
			27NOV2010	YES	8:15	YES	18:00	leichte Besserung mit der Zunge
			28NOV2010	YES	7:45	YES	17:30	leichte Besserung mit der Zunge
			29NOV2010	YES	7:45	YES	20:45	leichte Besserung mit der Zunge
			30NOV2010	YES	7:45	YES	17:30	Keine Beschwerden
			01DEC2010	YES	7:45	YES	17:30	Keine Beschwerden
			02DEC2010	YES	7:45	YES	17:30	Keine Beschwerden
			03DEC2010	YES	7:45	YES	17:30	Keine Beschwerden
			04DEC2010	YES	8:10	YES	18:00	Keine Beschwerden
			05DEC2010	YES	8:00	YES	17:30	Keine Beschwerden
			06DEC2010	YES	7:15	YES	17:30	Keine Beschwerden
			07DEC2010	YES	7:30	YES	17:30	Keine Beschwerden
			08DEC2010	YES	6:45	YES	17:30	Problem Zunge !? sonst keine Beschwerden
			09DEC2010	YES	7:30	YES	17:30	Problem Zunge !? sonst keine Beschwerden
			10DEC2010	YES	7:30	YES	17:30	Keine Beschwerden
			11DEC2010	YES	7:30	YES	18:00	Keine Beschwerden
			12DEC2010	YES	8:15	YES	18:00	Keine Beschwerden
			13DEC2010	YES		YES	17:30	Keine Beschwerden
			13DEC2010	YES	7:30			

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	080	13	14DEC2010	YES	7:15	YES	17:30	Keine Beschwerden
			15DEC2010	YES	7:45	YES	18:00	Keine Beschwerden
			16DEC2010	YES	7:45	YES	17:30	Körperlich keine Beschwerden
			17DEC2010	YES	7:45		18:00	Körperlich keine Beschwerden
			18DEC2010	YES	8:00	YES	18:00	Körperlich keine Beschwerden
			19DEC2010	YES	8:00	YES	17:30	Leichte Verschlechterung? Zeitabläufe Std. - Tag
			20DEC2010	YES	7:30	YES	17:30	Leichte Verschlechterung? Problem - Tagabläufe Wochentag
			21DEC2010	YES	7:30			Tick-Verschlechtert, Problem mit Zahlen
			22DEC2010	YES	7:30	YES	18:15	Keine großen Aussetzer
			23DEC2010	YES	7:30	YES	17:30	Übergeben im Auto/Angst?
			24DEC2010	YES	7:30	YES	17:30	Enkelkinder da, bisschen Durcheinander
			25DEC2010	YES	8:15	YES	17:30	Fernsehen kaum interesse. Früh ins Bett.
			26DEC2010	YES	8:00		17:30	Heute alles ok.
			27DEC2010	YES	8:00	YES	18:00	Bring Realität ducinander. Sucht ihre Kinder.
			28DEC2010	YES	7:30		17:30	Verwirrt. Fremde Leute sind bei uns.
			29DEC2010	YES	16:30	YES	20:00	Besprechung Dr. Hoffmann St. Josef Krankenhaus. Heute mit meine Frau ok.
			30DEC2010	YES	7:45	YES	17:30	Heute etwas besser. Mehrmals wo haben wir unser Auto stehen.
			31DEC2010	YES	8:30	YES	17:30	Leute bei uns. Es geht.
			01JAN2011	YES	8:00	YES	17:30	Ein bisschen Durcheinander
			02JAN2011	YES	8:00	YES	22:00	Vergessen die Tablette zu geben (17:30)
			03JAN2011	YES	8:00	YES	17:30	Nur ein bisschen Durcheinander

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	080	13	04JAN2011	YES	8:00	YES	17:30	Zum Hausarzt Dr. Meyer. Dr. H. Laborwerte nicht ok. Nierenwerte zu hoch.
			05JAN2011	YES	7:45		17:30	Es ging ihr schlecht, alles vergessen
			06JAN2011	YES	7:45	YES	17:30	Heute ging es ihr etwas besser.
			07JAN2011	YES	7:30	YES	17:30	Dr. Meyer 08:00 Labor etwas besser
			08JAN2011	YES	8:15	YES	17:30	Es geht ihr etwas besser.
			09JAN2011	YES	7:30	YES	17:30	Durcheinander besonders abends. Geht früh ins Bett 20:00.
			10JAN2011	YES	7:15	YES	17:30	Heute ging es mit ihr. Abends sehr müde.
			11JAN2011	YES	8:00	YES	17:30	Ganzen Tag stark durcheinander. Töchter mussten kommen.
			12JAN2011	YES	7:10		17:30	Es geht ihr etwas besser.
			13JAN2011	YES	6:30	YES	17:30	Dr. Heinefetter Rücksprache Cymbalta auf 60 mg. Es geht ihr etwas besser.
			14JAN2011	YES	7:20	YES		Abends total daneben. Sie wohnt nicht hier.
			15JAN2011	YES	8:00	YES	18:00	Es geht ihr nicht besser.
			16JAN2011	YES	8:00	YES	17:45	Packt alles in die Reisetasche. Ist nur am suchen.
			17JAN2011	YES	7:30	YES	17:45	Weint warum muss ich diese Krankheit bekommen.
			18JAN2011	YES	7:45	YES	17:30	Geht sehr früh ins Bett. 19:00 müde.
			19JAN2011	YES	7:30	YES	18:00	Heute ging es etwas besser.
			20JAN2011	YES	7:45	YES	17:30	Begegnung für Demens. Altenheim Tendorfer Str.
			21JAN2011	YES	7:45	YES	17:30	Abends eine Tablette vergessen.
			22JAN2011	YES	10:30	YES	20:00	2 Std. nach Frühst. Tablette. Wollte im Bett bleiben.
			23JAN2011	YES	7:30	YES	18:00	War wieder zu Hause (Hessenland). Taschen gepackt.

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	080	13	24JAN2011	YES	8:00	YES	17:45	Früh ins Bett 19:00. Lebt zu Hause im Hessenland.
			25JAN2011	YES	7:45	YES	17:30	Packt die Tasche, weint u. w. ins Hessenland. Eltern.
			26JAN2011	YES	7:30	YES	17:30	Heute ging es?!
			27JAN2011	YES	7:45	YES	17:30	Weinte. Tasche gepackt. Hessenland fahren. Geschwistern.
			28JAN2011	YES	7:45	YES	17:45	Treff für Demenzkranke. 2 Std. ohne Probleme.
			29JAN2011		7:45	YES	17:30	Keine Probleme! Früh zu Bett.
			30JAN2011	YES	8:00	YES	17:30	Heute sehr schlimm. Sie hat mich nicht erkannt. Tochter musste k.
			31JAN2011	YES	8:00	YES	17:30	Heute mit keine Probleme.
			01FEB2011	YES	8:00	YES	17:30	Tasche verlegt. Total daneben.
			02FEB2011	YES		YES	18:00	Bis zum Abend ging es einigermaßen gut. Tochter musste kommen.
			03FEB2011	YES	8:00			Mit der Schwester ins Hessenland gefahren. 2 Tage weg. Tabletten mitgenommen.
			04FEB2011	YES	8:00			
			05FEB2011	YES				Tabletten im Hessenland eingenommen. Keine großen Probleme.
			06FEB2011	YES	8:30	YES	17:45	Ganzen Tag ok?!? Abends war ich ihr fremd. Tochter gekommen.
			07FEB2011	YES	7:10	YES	18:00	Heute keine großen Probleme.
			08FEB2011	YES	8:00	YES	18:00	Hat ihre Schwester Elf. im Kopf. Probleme.
			09FEB2011	YES	7:30			

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	080	13	09FEB2011			YES	17:30	St Josef Hospital Studie Untersuchung 4 1/2 Std. / überfordert!
			10FEB2011	YES	7:15	YES	18:00	Der Tag ohne große Probleme
			11FEB2011	YES	7:45	YES	17:15	Heute ein ganz schlechter Tag! Zeitweise erkannte sie mich nicht. Tochter musste kommen.
			12FEB2011	YES	7:15	YES	18:00	Keine große Probleme
			13FEB2011	YES	8:00	YES	17:30	Heute Probleme. Mich nicht erkannt! Früh ins Bett.
			14FEB2011	YES	7:30	YES	18:00	Ganzen Vormittag Geld und Schlüssel gesucht.
			15FEB2011	YES				Vormittag, Leute zu Besuch?? Muß für sie kochen! Total daneben.
			16FEB2011	YES	7:30	YES	18:00	Keine große Probleme
			17FEB2011	YES	7:45	YES	19:30	Nicht erkannt. Nachbar hat sie geholt. Ich soll gehen. Tablette 2 Std. später/n. Essen
			18FEB2011	YES	7:45	YES	18:00	Keine große Probleme
			19FEB2011	YES	7:45	YES	18:00	Keine große Probleme
			20FEB2011	YES	8:00	YES	17:45	Heute den ganzen Tag die Geldbörse gesucht. War total fertig.
			21FEB2011	YES	7:15		18:00	Keine große Probleme
			22FEB2011	YES	7:30	YES	18:00	Geldbörse, Sporthose gesucht. 2 Std.
			23FEB2011	YES	7:45	YES	18:00	Suchte den ganzen Nachmittag ihre Eltern.
			24FEB2011	YES	7:30	YES	18:00	Ganz schlimm. Ich war ein Fremder. Tochter musste kommen.
			25FEB2011	YES	7:30	YES	17:45	1 Std. weggefahren. Ich soll aus die Wohnung. Polizei

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	080	13	26FEB2011	YES				Morgens total daneben. Menschen sind hir. Wir haben beschlossen sie ins Krankh. zu bringen.
	081	17	14OCT2010			YES	19:00	
			15OCT2010		7:00	YES	19:00	
			16OCT2010	YES	7:00	YES	19:00	
			17OCT2010	YES	7:00	YES	19:00	
			18OCT2010	YES	7:00	YES	19:00	
			19OCT2010	YES	7:00	YES	19:00	
			20OCT2010	YES	7:00	YES	19:00	
			21OCT2010	YES	7:00	YES	19:00	
			22OCT2010	YES	7:00	YES	19:00	
			23OCT2010	YES	7:00	YES	19:00	
			24OCT2010	YES	7:00	YES	19:00	
			25OCT2010	YES	7:00	YES	19:00	
			26OCT2010	YES	7:00	YES	19:00	
			27OCT2010	YES	7:00	YES	19:00	
			28OCT2010	YES	7:00	YES	19:00	
			29OCT2010	YES	7:00	YES	19:00	
			30OCT2010	YES	7:00	YES	19:00	
			31OCT2010	YES	7:00	YES	19:00	
			01NOV2010	YES	7:00	YES	19:00	
			02NOV2010	YES	7:00	YES	19:00	
			03NOV2010	YES	7:00	YES	19:00	
			04NOV2010	YES	7:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	05NOV2010	YES	7:00	YES	19:00	
			06NOV2010	YES	7:00	YES	19:00	
			07NOV2010	YES	7:00	YES	19:00	
			08NOV2010	YES	7:00	YES	19:00	
			09NOV2010	YES	7:00	YES	19:00	
			10NOV2010	YES	7:00	YES	19:00	
			11NOV2010	YES	7:00	YES	19:00	
			12NOV2010	YES	7:00	YES	19:00	
			13NOV2010	YES	7:00	YES	19:00	
			14NOV2010	YES	7:00	YES	19:00	
			15NOV2010	YES	7:00			
			15NOV2010			YES	19:00	
			16NOV2010	YES	7:00	YES	19:00	
			17NOV2010	YES	7:00	YES	19:00	
			18NOV2010	YES	7:00	YES	19:00	
			19NOV2010	YES	7:00	YES	19:00	
			20NOV2010	YES	7:00	YES	19:00	
			21NOV2010	YES	7:00	YES	19:00	
			22NOV2010	YES	7:00	YES	19:00	
			23NOV2010	YES	7:00	YES	19:00	
			24NOV2010	YES	7:00	YES	19:00	
			25NOV2010	YES	7:00	YES	19:00	
			26NOV2010	YES	7:00	YES	19:00	
			27NOV2010	YES	7:00	YES	19:00	
			28NOV2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	29NOV2010	YES	7:00	YES	19:00	
			30NOV2010	YES	7:00	YES	19:00	
			01DEC2010	YES	7:00	YES	19:00	
			02DEC2010	YES	7:00	YES	19:00	
			03DEC2010	YES	7:00	YES	19:00	
			04DEC2010	YES	7:00	YES	19:00	
			05DEC2010	YES	7:00	YES	19:00	
			06DEC2010	YES	7:00	YES	19:00	
			07DEC2010	YES	7:00	YES	19:00	
			08DEC2010	YES	7:00	YES	19:00	
			09DEC2010	YES	7:00	YES	19:00	
			10DEC2010	YES	7:00	YES	19:00	
			11DEC2010	YES	7:00	YES	19:00	
			12DEC2010	YES	7:00	YES	19:00	
			13DEC2010	YES	7:00	YES	19:00	
			14DEC2010	YES	7:00	YES	19:00	
			15DEC2010	YES	7:00	YES	19:00	
			16DEC2010	YES	7:00	YES	19:00	
			17DEC2010	YES	7:00	YES	19:00	
			18DEC2010	YES	7:00	YES	19:00	
			19DEC2010	YES	7:00	YES	19:00	
			20DEC2010	YES	7:00	YES	19:00	
			21DEC2010	YES	7:00	YES	19:00	
			22DEC2010	YES	7:00	YES	19:00	
			23DEC2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	24DEC2010	YES	7:00	YES	19:00	
			25DEC2010	YES	7:00	YES	19:00	
			26DEC2010	YES	7:00	YES	19:00	
			27DEC2010	YES	7:00	YES	19:00	
			28DEC2010	YES	7:00	YES	19:00	
			29DEC2010	YES	7:00	YES	19:00	
			30DEC2010		7:00		19:00	
			31DEC2010		7:00		19:00	
			01JAN2011		7:00		19:00	
			02JAN2011		7:00		19:00	
			03JAN2011		7:00		19:00	
			04JAN2011		7:00		19:00	
			05JAN2011		7:00		19:00	
			06JAN2011		7:00		19:00	
			07JAN2011		7:00		19:00	
			08JAN2011		7:00		19:00	
			09JAN2011		7:00		19:00	
			10JAN2011	YES	7:00			
			11JAN2011			YES	19:00	
			12JAN2011	YES	8:00	YES	19:00	
			13JAN2011	YES	8:00		19:00	
			14JAN2011	YES	8:00	YES	19:00	
			15JAN2011	YES	8:00	YES	19:00	
			16JAN2011	YES	8:00	YES	19:00	
			17JAN2011	YES	9:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	18JAN2011	YES	8:00	YES	19:00	
			19JAN2011	YES	8:00	YES	20:00	
			20JAN2011	YES	8:00	YES	20:00	
			21JAN2011	YES	8:00	YES	20:00	
			22JAN2011	YES	8:00	YES	20:00	
			23JAN2011	YES	8:00	YES	20:00	
			24JAN2011	YES	8:00	YES	20:00	
			25JAN2011	YES	8:00	YES	20:00	
			26JAN2011	YES	8:00	YES	20:00	
			27JAN2011	YES	8:00	YES	20:00	
			28JAN2011	YES	8:00	YES	20:00	08:00 20:00
			29JAN2011	YES	8:00	YES	20:00	
			30JAN2011	YES	8:00	YES	20:00	
			31JAN2011	YES	8:00	YES	20:00	
			01FEB2011	YES	8:00	YES	20:00	
			02FEB2011	YES	8:00	YES	20:00	
			03FEB2011	YES	8:00	YES	20:00	
			04FEB2011	YES	8:00	YES	20:00	
			05FEB2011	YES	8:00	YES	20:00	
			06FEB2011	YES	8:00	YES	20:00	08:00 20:00
			07FEB2011	YES	8:00	YES	20:00	
			08FEB2011	YES	8:00	YES	20:00	
			09FEB2011	YES	8:00	YES	20:00	
			10FEB2011	YES	8:00	YES	20:00	
			11FEB2011	YES	8:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	12FEB2011	YES	8:00	YES	20:00	
			13FEB2011	YES	8:00	YES	20:00	
			14FEB2011	YES	8:00	YES	20:00	
			15FEB2011	YES	7:30	YES	19:00	07:30 + 19:00 bleiben als Zeit
			16FEB2011	YES	7:30	YES	19:00	
			17FEB2011	YES	7:30	YES	19:00	
			18FEB2011	YES	7:30	YES	19:00	
			19FEB2011	YES	7:30	YES	19:00	
			20FEB2011	YES	7:30	YES	19:00	
			21FEB2011	YES	7:30	YES	19:00	
			22FEB2011	YES	7:30	YES	19:00	
			23FEB2011	YES	7:30	YES	19:00	
			24FEB2011	YES	7:30	YES	19:00	
			25FEB2011	YES	7:30	YES	19:00	
			26FEB2011	YES	7:30	YES	19:00	
			27FEB2011	YES	7:30	YES	19:00	
			28FEB2011	YES	7:30	YES	19:00	
			01MAR2011	YES	7:30	YES	19:00	
			02MAR2011	YES	7:30	YES	19:00	
			03MAR2011	YES	7:30	YES	19:00	
			04MAR2011	YES	7:30	YES	19:00	
			05MAR2011	YES	7:30	YES	19:00	
			06MAR2011	YES	7:30	YES	19:00	
			07MAR2011	YES	7:30	YES	19:00	
			08MAR2011	YES	7:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	09MAR2011	YES	7:30	YES	19:00	
			10MAR2011	YES	7:30	YES	19:00	
			11MAR2011	YES	7:30	YES	19:00	
			12MAR2011	YES	7:30	YES	19:00	
			13MAR2011	YES	7:30	YES	19:00	
			14MAR2011		7:30		19:00	07:30 - 19:00
			15MAR2011		7:30		19:00	
			16MAR2011		7:30		19:00	
			17MAR2011		7:30		19:00	
			18MAR2011		7:30		19:00	
			19MAR2011		7:30		19:00	
			20MAR2011		7:30		19:00	
			21MAR2011		7:30		19:00	
			22MAR2011		7:30		19:00	
			23MAR2011	YES	7:30	YES	19:00	07:30 - 19:00
			24MAR2011	YES	7:30	YES	19:00	
			25MAR2011	YES	7:30	YES	19:00	
			26MAR2011	YES	7:30	YES	19:00	
			27MAR2011	YES	7:30	YES	19:00	
			28MAR2011	YES	7:30	YES	19:00	
			29MAR2011	YES	7:30	YES	19:00	
			30MAR2011	YES	7:30	YES	19:00	
			31MAR2011	YES	7:30	YES	19:00	
			01APR2011	YES	7:30	YES	19:00	
			02APR2011	YES	7:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	03APR2011	YES	7:30	YES	19:00	
			04APR2011	YES	7:30	YES	19:00	
			05APR2011	YES	7:30	YES	19:00	
			06APR2011	YES	7:00			
			07APR2011			YES	19:30	06.04.11 abend
			08APR2011	YES	8:00	YES	19:32	
			09APR2011	YES	8:00	YES	19:33	
			10APR2011	YES	8:15	YES	19:34	
			11APR2011	YES	8:15	YES	19:30	
			12APR2011	YES	8:00	YES	19:30	
			13APR2011	YES	7:45	YES	19:35	
			14APR2011	YES	7:50	YES	19:30	
			15APR2011	YES	7:55	YES	19:35	
			16APR2011	YES	8:30	YES	19:00	
			17APR2011	YES	8:15	YES	19:30	
			18APR2011	YES	8:15	YES	19:15	
			19APR2011	YES	8:10	YES	19:15	
			20APR2011	YES	8:10	YES	19:30	
			21APR2011	YES	8:15	YES	19:20	
			22APR2011	YES	8:25	YES	19:20	
			23APR2011	YES	8:00	YES	19:25	
			24APR2011	YES	8:00	YES	19:15	
			25APR2011	YES	7:45	YES	19:15	
			26APR2011	YES	7:50	YES	19:30	
			27APR2011	YES	7:50	YES	19:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	28APR2011	YES	7:45	YES	19:50	
			29APR2011	YES	8:00	YES	19:50	
			30APR2011	YES	8:15	YES	19:50	
			01MAY2011	YES	8:15	YES	19:50	
			02MAY2011	YES	8:20	YES	20:00	
			03MAY2011	YES	8:15	YES	20:00	
			04MAY2011	YES	7:45	YES	20:00	
			05MAY2011	YES	7:45	YES	20:00	
			06MAY2011	YES	7:45	YES	20:00	
			07MAY2011	YES	7:45	YES	20:00	
			08MAY2011	YES	8:00	YES	20:00	
			09MAY2011	YES	8:00	YES	19:50	
			10MAY2011	YES	8:00	YES	19:50	
			11MAY2011	YES	7:50	YES	19:51	
			12MAY2011	YES	7:50	YES	19:52	
			13MAY2011	YES	7:45	YES	20:00	
			14MAY2011	YES	7:45	YES	20:00	
			15MAY2011	YES	7:45	YES	20:10	
			16MAY2011	YES	7:50	YES	20:10	
			17MAY2011	YES	7:30	YES	20:15	
			18MAY2011	YES	7:30	YES	20:15	
			19MAY2011	YES	7:45	YES	20:15	
			20MAY2011	YES	7:30	YES	20:30	
			21MAY2011	YES	7:30	YES	20:30	
			22MAY2011	YES	7:30	YES	20:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	23MAY2011	YES	7:30	YES	20:15	
			24MAY2011	YES	7:30	YES	20:15	
			25MAY2011	YES	7:35	YES	20:20	
			26MAY2011	YES	7:35	YES	20:20	
			27MAY2011	YES	7:45	YES	20:15	
			28MAY2011	YES	7:45	YES	20:14	
			29MAY2011	YES	7:50	YES	20:10	
			30MAY2011	YES	7:50	YES	20:10	
			31MAY2011	YES	7:30	YES	20:15	
			01JUN2011	YES	7:30	YES	20:15	
			02JUN2011	YES	7:30	YES	20:10	
			03JUN2011	YES	7:30	YES	20:10	
			04JUN2011	YES	7:35	YES	20:20	
			05JUN2011	YES	7:40	YES	20:20	
			06JUN2011	YES	7:40	YES	20:10	
			07JUN2011	YES	7:30	YES	20:15	
			08JUN2011	YES	7:30	YES	20:16	
			09JUN2011	YES	7:30	YES	20:30	
			10JUN2011	YES	7:30	YES	20:30	
			11JUN2011	YES	7:35	YES	20:10	
			12JUN2011	YES	7:30	YES	20:10	
			13JUN2011	YES	7:35	YES	20:15	
			14JUN2011	YES	7:40	YES	20:16	
			15JUN2011	YES	7:45	YES	20:00	
			16JUN2011	YES	7:30	YES	20:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	17JUN2011	YES	7:45	YES	20:15	
			18JUN2011	YES	7:30	YES	20:10	
			19JUN2011	YES	7:30	YES	20:00	
			20JUN2011	YES	7:30			
			20JUN2011			YES	19:30	
			21JUN2011	YES	8:00	YES	18:30	
			22JUN2011	YES	8:00	YES	19:30	
			23JUN2011	YES	8:30	YES	19:50	
			24JUN2011	YES	8:35	YES	19:50	
			25JUN2011	YES	8:30	YES	19:50	
			26JUN2011	YES	8:30	YES	19:30	
			27JUN2011	YES	8:30	YES	19:30	
			28JUN2011	YES	8:40		19:30	
			29JUN2011	YES	8:00	YES	19:30	
			30JUN2011	YES	8:20	YES	19:30	
			01JUL2011	YES	8:20	YES	19:40	
			02JUL2011	YES	8:00	YES	19:20	
			03JUL2011	YES	8:10	YES	19:20	
			04JUL2011	YES	8:10	YES	19:30	
			05JUL2011	YES	8:15	YES	19:30	
			06JUL2011	YES	8:15	YES	19:40	
			07JUL2011	YES	8:20	YES	19:30	
			08JUL2011	YES	7:45	YES	19:45	
			09JUL2011	YES	7:20	YES	19:20	
			10JUL2011	YES	7:45	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	11JUL2011	YES	7:30	YES	19:30	
			12JUL2011	YES	7:45	YES	19:45	
			13JUL2011	YES	7:30	YES	19:45	
			14JUL2011	YES	7:30	YES	19:30	
			15JUL2011	YES	7:45	YES	19:30	
			16JUL2011	YES	7:45	YES	19:30	
			17JUL2011	YES	8:00	YES	19:00	
			18JUL2011	YES	8:00	YES	19:00	
			19JUL2011	YES	7:50	YES	19:10	
			20JUL2011	YES	7:50	YES	19:10	
			21JUL2011	YES	7:50	YES	19:10	
			22JUL2011	YES	7:50	YES	19:15	
			23JUL2011	YES	7:45	YES	19:15	
			24JUL2011	YES	7:45	YES	19:15	
			25JUL2011	YES	7:45	YES	19:15	70 Tabl.
			26JUL2011	YES	7:45	YES	19:10	
			27JUL2011	YES	7:45	YES	19:10	
			28JUL2011	YES	7:45	YES	19:10	
			29JUL2011	YES	7:45	YES	19:15	
			30JUL2011	YES	7:50	YES	19:20	
			31JUL2011	YES	7:50	YES	19:20	
			01AUG2011	YES	7:50	YES	19:20	
			02AUG2011	YES	7:30	YES	19:30	
			03AUG2011	YES	7:50	YES	19:30	
			04AUG2011	YES	7:45	YES	19:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	05AUG2011	YES	7:50	YES	19:15	
			06AUG2011	YES	7:15	YES	19:15	
			07AUG2011	YES	7:30	YES	19:30	
			08AUG2011	YES	7:10	YES	19:10	
			09AUG2011	YES	7:30	YES	19:10	
			10AUG2011	YES	7:20	YES	19:20	
			11AUG2011	YES	7:30	YES	19:45	
			12AUG2011	YES	7:30	YES	19:45	
			13AUG2011	YES	7:45	YES	19:30	
			14AUG2011	YES	7:15	YES	19:30	
			15AUG2011	YES	7:30	YES	19:30	
			16AUG2011	YES	7:30	YES	19:30	
			17AUG2011	YES	7:30	YES	19:30	
			18AUG2011	YES	7:45	YES	19:30	
			19AUG2011	YES	7:20	YES	19:30	
			20AUG2011	YES	7:45	YES	19:20	
			21AUG2011	YES	7:30	YES	19:20	
			22AUG2011	YES	7:45	YES	19:30	
			23AUG2011	YES	7:20	YES	19:20	
			24AUG2011	YES	7:30	YES	19:20	
			25AUG2011	YES	7:00	YES	19:30	
			26AUG2011	YES	7:30	YES	19:40	
			27AUG2011	YES	7:30	YES	19:40	
			28AUG2011	YES	7:30	YES	19:20	
			29AUG2011	YES	7:20	YES	19:20	/700

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	30AUG2011	YES	7:30	YES	19:30	
			31AUG2011	YES	7:45	YES	19:15	
			01SEP2011	YES	7:20	YES	19:15	
			02SEP2011	YES	7:30	YES	19:20	
			03SEP2011	YES	7:45	YES	19:45	
			04SEP2011	YES	7:20	YES	19:30	
			05SEP2011	YES	7:30	YES	19:30	
			06SEP2011	YES	7:30	YES	19:40	
			07SEP2011	YES	7:30	YES	19:45	
			08SEP2011	YES	7:30	YES	19:20	
			10SEP2011	YES	7:15	YES	19:30	
			11SEP2011	YES	7:45	YES	19:45	
			12SEP2011	YES	7:45	YES	19:30	
			13SEP2011	YES	7:30	YES	19:45	
			14SEP2011	YES	7:30	YES	19:20	
			15SEP2011	YES	7:30	YES	19:20	
			16SEP2011	YES	7:45	YES	19:30	
			17SEP2011	YES	7:45	YES	19:30	
			18SEP2011	YES	7:20	YES	19:30	
			19SEP2011	YES	7:30	YES	19:30	
			20SEP2011	YES	7:30	YES	19:30	
			21SEP2011	YES	7:30	YES	19:45	
			22SEP2011	YES	7:30	YES	19:40	
			23SEP2011	YES	7:45	YES	19:40	
			24SEP2011	YES	7:50	YES	19:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	25SEP2011	YES	7:40	YES	19:20	
			26SEP2011	YES	7:40	YES	19:40	
			27SEP2011	YES	7:40	YES	19:45	
			28SEP2011	YES	7:30	YES	19:30	
			29SEP2011	YES	7:30	YES	19:30	
			30SEP2011	YES	7:30	YES	19:30	
			01OCT2011	YES	7:45	YES	19:30	
			02OCT2011	YES	7:45	YES	19:30	
			03OCT2011	YES	7:30	YES	19:30	
			04OCT2011	YES	7:30	YES	19:00	/701
			05OCT2011	YES	7:30	YES	19:00	
			06OCT2011	YES	7:30	YES	19:00	
			07OCT2011	YES	7:45	YES	19:30	
			08OCT2011	YES	7:50	YES	19:35	
			09OCT2011	YES	7:50	YES	19:30	
			10OCT2011	YES	8:00	YES	19:30	
			11OCT2011	YES	8:00	YES	19:45	
			12OCT2011	YES	8:00	YES	19:50	
			13OCT2011	YES	8:05	YES	19:50	
			14OCT2011	YES	7:55	YES	19:45	
			15OCT2011	YES	7:55	YES	20:00	
			16OCT2011	YES	7:50	YES	19:20	
			17OCT2011	YES	7:45	YES	19:20	
			18OCT2011	YES	7:45	YES	19:20	
			19OCT2011	YES	8:00	YES	19:45	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	081	17	20OCT2011	YES	8:00	YES	19:45	
			21OCT2011	YES	8:00	YES	19:50	
			22OCT2011	YES	8:05	YES	19:50	
			23OCT2011	YES	8:15	YES	20:00	
			24OCT2011	YES	8:15	YES	20:00	
	083	17	08DEC2010			YES	19:30	
			09DEC2010	YES	8:00	YES	19:30	
			10DEC2010	YES	8:00	YES	19:31	
			11DEC2010	YES	8:10	YES	19:30	
			12DEC2010	YES	8:10	YES	19:30	
			13DEC2010	YES	8:20	YES	19:30	
			14DEC2010	YES	8:15	YES	19:32	
			15DEC2010	YES	8:10	YES	19:30	
			16DEC2010	YES	8:00	YES	19:06	
			17DEC2010	YES	8:00	YES	20:00	
			18DEC2010	YES	8:00	YES	20:00	
			19DEC2010	YES	8:00	YES	20:15	
			20DEC2010	YES	8:10	YES	19:30	
			21DEC2010	YES	8:10	YES	19:45	
			22DEC2010	YES	8:20	YES	19:45	
			23DEC2010	YES	8:20	YES	19:30	
			24DEC2010	YES	8:30	YES	20:00	
			25DEC2010	YES	8:30	YES	20:06	
			26DEC2010	YES	8:30	YES	20:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	27DEC2010	YES	8:30	YES	20:00	
			28DEC2010	YES	8:45	YES	19:30	
			29DEC2010	YES	8:30	YES	19:30	
			30DEC2010	YES	8:00	YES	19:30	
			31DEC2010	YES	8:30	YES	20:30	
			01JAN2011	YES	9:00	YES	20:00	
			02JAN2011	YES	9:00	YES	20:00	
			03JAN2011	YES	8:00	YES	19:30	
			04JAN2011	YES	8:00	YES	19:30	
			05JAN2011	YES	8:00	YES	19:30	
			06JAN2011	YES	8:10	YES	19:30	
			07JAN2011	YES	7:30	YES	19:31	
			08JAN2011	YES	7:30	YES	19:45	
			09JAN2011	YES	7:30	YES	18:55	
			10JAN2011	YES	7:30	YES	18:50	
			11JAN2011	YES	7:45	YES	19:00	
			12JAN2011	YES	7:30	YES	19:00	
			13JAN2011	YES	7:30	YES	19:01	
			14JAN2011	YES	7:30	YES	19:10	
			15JAN2011	YES	8:00	YES	19:20	
			16JAN2011	YES	8:00	YES	19:20	
			17JAN2011	YES	8:00	YES	19:30	
			18JAN2011	YES	8:10	YES	19:50	
			19JAN2011	YES	8:15	YES	19:50	
			20JAN2011	YES	8:15	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	21JAN2011	YES	7:30	YES	19:30	
			22JAN2011	YES	7:30	YES	19:30	
			23JAN2011	YES	8:00	YES	19:00	
			24JAN2011	YES	8:10	YES	19:30	
			25JAN2011	YES	7:45	YES	19:00	
			26JAN2011	YES	7:45	YES	20:00	
			27JAN2011	YES	7:45	YES	20:00	
			28JAN2011	YES	7:45	YES	20:00	
			29JAN2011	YES	7:30	YES	20:00	
			30JAN2011	YES	7:30	YES	19:00	
			31JAN2011	YES	7:30	YES	19:00	
			01FEB2011	YES	7:30	YES		
			02FEB2011	YES	7:30			
			02FEB2011			YES	20:00	
			03FEB2011	YES	8:00	YES	20:00	
			04FEB2011	YES	8:00	YES	20:00	
			05FEB2011	YES	8:00	YES	20:00	
			06FEB2011	YES	8:00	YES	20:00	
			07FEB2011	YES	8:00	YES	20:00	
			08FEB2011	YES	8:00	YES	20:00	
			09FEB2011	YES	8:00	YES	20:00	
			10FEB2011	YES	8:00	YES	20:00	
			11FEB2011	YES	8:00	YES	19:00	
			12FEB2011	YES	8:00	YES	19:00	
			13FEB2011	YES	8:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	14FEB2011	YES	8:00	YES	19:00	
			15FEB2011	YES	8:00	YES	19:00	
			16FEB2011	YES	8:00	YES	19:00	
			17FEB2011	YES	8:00	YES	19:00	
			18FEB2011	YES	8:00	YES	19:00	
			19FEB2011	YES	8:00	YES	19:00	
			20FEB2011	YES	8:00	YES	19:00	
			21FEB2011	YES	8:00	YES	20:00	
			22FEB2011	YES	8:00	YES	19:30	
			23FEB2011	YES	8:00	YES	19:30	
			24FEB2011	YES	8:00	YES	19:30	
			25FEB2011	YES	8:00	YES	19:30	
			26FEB2011	YES	8:00	YES	19:30	
			27FEB2011	YES	8:00	YES	19:30	
			28FEB2011	YES	8:00	YES	19:30	
			10MAR2011	YES	8:00	YES	19:30	
			11MAR2011	YES	8:00	YES	19:30	
			12MAR2011	YES	8:00	YES	19:30	
			13MAR2011	YES	8:00	YES	19:30	
			14MAR2011	YES	8:00	YES	19:30	
			15MAR2011	YES	8:00	YES	20:01	
			16MAR2011	YES	8:00	YES	20:00	
			17MAR2011	YES	8:00	YES	20:01	
			18MAR2011	YES	8:00	YES	20:20	
			20MAR2011	YES	8:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	20MAR2011	YES	8:00	YES	20:00	
			21MAR2011	YES	8:00	YES	20:00	
			21MAR2011	YES	8:00	YES	20:00	
			22MAR2011	YES	8:00	YES	20:00	
			22MAR2011	YES	8:00	YES	20:00	
			23MAR2011	YES	8:00	YES	20:00	
			23MAR2011	YES	8:00	YES	20:00	
			24MAR2011	YES	8:00	YES	20:00	
			24MAR2011	YES	8:00	YES	20:00	
			25MAR2011	YES	8:00	YES	20:00	
			25MAR2011	YES	8:00	YES	20:00	
			26MAR2011	YES	8:00	YES	20:00	
			26MAR2011	YES	8:00	YES	20:00	
			27MAR2011	YES	8:00	YES	20:00	
			27MAR2011	YES	8:00	YES	20:00	
			28MAR2011	YES	8:00	YES	20:00	
			28MAR2011	YES	8:00	YES	20:00	
			29MAR2011	YES	8:00	YES	20:00	
			30MAR2011	YES	8:00	YES	20:00	
			31MAR2011	YES	8:00	YES	20:00	
			01APR2011	YES	8:00	YES	20:00	
			02APR2011	YES	8:00	YES	20:00	
			03APR2011	YES	8:00	YES	20:00	
			04APR2011	YES	8:00	YES	20:00	
			05APR2011	YES	8:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	06APR2011	YES	8:00	YES	20:00	
			07APR2011	YES	8:00	YES	19:45	
			08APR2011	YES	8:00	YES	19:45	
			09APR2011	YES	8:00	YES	19:45	
			10APR2011	YES	8:00	YES	19:45	
			11APR2011	YES	8:00	YES	19:45	
			12APR2011	YES	8:00	YES	19:45	
			13APR2011	YES	8:00	YES	19:30	
			14APR2011	YES	8:00	YES	19:30	
			15APR2011	YES	8:00	YES	19:30	
			16APR2011	YES	8:00	YES	19:30	
			17APR2011	YES	8:00	YES	19:30	
			18APR2011	YES	8:00	YES	19:30	
			19APR2011	YES	8:00	YES	19:30	
			20APR2011	YES	8:00	YES	19:30	
			21APR2011	YES	8:00	YES	19:30	
			22APR2011	YES	8:00	YES	19:30	
			23APR2011	YES	8:00	YES	19:30	
			24APR2011	YES	8:00	YES	19:30	
			25APR2011	YES	8:00	YES	19:00	
			26APR2011	YES	7:30	YES	19:00	
			26APR2011	YES	7:30			
			27APR2011	YES	7:30	YES	19:00	
			28APR2011	YES	7:30	YES	19:15	
			29APR2011	YES	7:30	YES	19:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	30APR2011	YES	7:25	YES	19:15	
			01MAY2011	YES	7:26	YES	19:16	
			02MAY2011	YES	7:25	YES	19:00	
			03MAY2011	YES	7:30	YES	19:00	
			04MAY2011	YES	7:30	YES	19:00	
			05MAY2011	YES	7:30	YES	19:05	
			06MAY2011	YES	7:15	YES	19:00	
			07MAY2011	YES	7:15	YES	19:15	
			08MAY2011	YES	7:30	YES	19:15	
			09MAY2011	YES	7:31	YES	19:45	
			10MAY2011	YES	7:30	YES	19:45	
			11MAY2011	YES	7:30	YES	19:45	
			12MAY2011	YES	7:32	YES	19:50	
			13MAY2011	YES	7:35	YES	19:30	
			14MAY2011	YES	7:30	YES	19:20	
			15MAY2011	YES	7:30	YES	19:30	
			16MAY2011	YES	7:30	YES	19:30	
			17MAY2011	YES	7:35	YES	19:30	
			18MAY2011	YES	7:35	YES	19:45	
			19MAY2011	YES	7:40	YES	19:45	
			20MAY2011	YES	7:40	YES	19:20	
			21MAY2011	YES	7:35	YES	19:20	
			22MAY2011	YES	7:30	YES	19:20	
			23MAY2011	YES	7:30	YES	19:50	
			24MAY2011	YES	7:30	YES	19:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	25MAY2011	YES	7:31	YES	19:55	
			26MAY2011	YES	7:35	YES	20:00	
			27MAY2011	YES	7:30	YES	20:00	
			28MAY2011	YES	7:40	YES	20:00	
			29MAY2011	YES	7:45	YES	19:50	
			30MAY2011	YES	7:30	YES	19:30	
			31MAY2011	YES	7:30	YES	19:30	
			01JUN2011		7:30		20:00	
			02JUN2011		7:30		19:40	
			03JUN2011		7:30		19:50	
			04JUN2011		7:35		19:50	
			05JUN2011		7:30		19:50	
			06JUN2011		7:35		19:45	
			07JUN2011		7:40		19:30	
			08JUN2011		7:45		19:30	
			09JUN2011		7:45		19:30	
			10JUN2011	YES	7:30	YES	19:30	
			11JUN2011	YES	7:30	YES	19:30	
			12JUN2011	YES	7:31	YES	19:40	
			13JUN2011	YES	7:40	YES	19:40	
			14JUN2011	YES	7:40	YES	19:45	
			15JUN2011	YES	7:30	YES	19:45	
			16JUN2011	YES	7:30	YES	19:45	
			17JUN2011	YES	7:30	YES	19:45	
			18JUN2011	YES	7:30	YES	19:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	19JUN2011	YES	7:30	YES	20:00	
			20JUN2011	YES	7:30	YES	20:00	
			21JUN2011	YES	7:30	YES	20:00	
			22JUN2011	YES	7:30	YES	20:05	
			23JUN2011	YES	7:30	YES	19:05	
			24JUN2011	YES	7:40	YES	19:30	
			25JUN2011	YES	7:40	YES	19:30	
			26JUN2011	YES	7:30	YES	19:40	
			27JUN2011	YES	7:00	YES	19:45	
			28JUN2011	YES	7:30	YES	19:30	
			29JUN2011	YES	7:30	YES	19:30	
			30JUN2011	YES	7:30	YES	19:45	
			01JUL2011	YES	7:40	YES	19:55	
			02JUL2011	YES	7:40	YES	19:45	
			03JUL2011	YES	7:30	YES	19:30	
			04JUL2011	YES	7:35	YES	19:30	
			05JUL2011	YES	7:40	YES	19:30	
			06JUL2011	YES	7:40	YES	19:45	
			07JUL2011	YES	7:30	YES	20:00	
			08JUL2011	YES	7:30	YES	20:00	
			09JUL2011	YES	7:30	YES	20:05	
			10JUL2011	YES	7:40	YES	20:05	
			11JUL2011	YES	7:40	YES	20:10	
			12JUL2011	YES	7:40	YES	20:10	
			13JUL2011	YES	7:35	YES	20:15	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	14JUL2011	YES	7:35	YES	20:00	
			15JUL2011	YES	7:40	YES	20:00	
			16JUL2011	YES	7:30	YES	20:00	
			17JUL2011	YES	7:30	YES	20:00	
			18JUL2011	YES	7:30	YES	20:00	
			19JUL2011	YES	7:30	YES	20:20	
			20JUL2011	YES	7:30	YES	20:00	
			21JUL2011	YES	7:30	YES	19:00	
			22JUL2011	YES	7:30	YES	19:50	
			23JUL2011	YES	7:30	YES	19:50	
			24JUL2011	YES	7:30	YES	20:00	
			25JUL2011	YES	7:15			
			25JUL2011	YES	7:30	YES	20:00	
			26JUL2011	YES	7:30	YES	20:00	
			27JUL2011	YES	7:30	YES	20:00	
			28JUL2011	YES	7:30	YES	20:00	
			29JUL2011	YES	7:50	YES	20:00	
			30JUL2011	YES	7:30	YES	20:00	
			31JUL2011	YES	7:45	YES	20:00	
			01AUG2011	YES	7:45	YES	20:00	
			02AUG2011	YES	7:50	YES	20:00	
			03AUG2011	YES	8:00	YES	20:00	
			04AUG2011	YES	8:00	YES	20:00	
			05AUG2011	YES	8:00	YES	20:00	
			06AUG2011	YES	8:00	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	07AUG2011	YES	8:00	YES	20:00	
			08AUG2011	YES	8:00	YES	20:00	
			09AUG2011	YES	8:00	YES	20:00	
			10AUG2011	YES	8:00	YES	20:00	
			11AUG2011	YES	8:00	YES	20:00	
			12AUG2011	YES	8:00	YES	20:00	
			13AUG2011	YES	8:00	YES	20:00	
			14AUG2011	YES	8:00	YES	20:00	
			15AUG2011	YES	8:00	YES	20:00	
			16AUG2011	YES	8:00	YES	20:00	
			17AUG2011	YES	8:00	YES	20:00	
			18AUG2011	YES	8:00	YES	20:00	
			19AUG2011	YES	8:00	YES	20:00	
			20AUG2011	YES	8:00	YES	20:00	
			21AUG2011	YES	8:00	YES	20:00	
			22AUG2011	YES	8:00	YES	20:00	
			23AUG2011	YES	8:00	YES	20:00	
			24AUG2011	YES	7:50	YES	20:00	
			25AUG2011	YES	7:50	YES	20:00	
			26AUG2011	YES	7:45	YES	20:00	
			27AUG2011	YES	7:45	YES	20:00	
			28AUG2011	YES	7:45	YES	20:00	
			29AUG2011	YES	7:45	YES	20:00	
			30AUG2011	YES	8:00	YES	20:00	
			31AUG2011	YES	8:15	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	01SEP2011	YES	8:15	YES	20:00	
			02SEP2011	YES	8:20	YES	20:00	
			03SEP2011	YES	8:00	YES	20:00	
			04SEP2011	YES	8:00	YES	20:00	
			05SEP2011	YES	8:00	YES	20:00	
			06SEP2011	YES	8:00	YES	20:00	
			07SEP2011	YES	8:00	YES	20:00	
			08SEP2011	YES	7:50	YES	20:00	
			09SEP2011	YES	7:50	YES	20:00	
			10SEP2011	YES	7:45	YES	20:00	
			11SEP2011	YES	7:45	YES	20:00	
			12SEP2011	YES	7:45	YES	20:00	
			13SEP2011	YES	8:00	YES	20:00	
			14SEP2011	YES	8:00	YES	20:00	
			15SEP2011	YES	8:00	YES	20:00	
			16SEP2011	YES	8:00	YES	20:00	
			17SEP2011	YES	7:45	YES	20:00	
			18SEP2011	YES	7:50	YES	20:00	
			19SEP2011	YES	7:50	YES	20:00	
			20SEP2011	YES	7:50	YES	20:00	
			21SEP2011	YES	7:50	YES	20:00	
			22SEP2011	YES	7:50	YES	20:00	
			23SEP2011	YES	7:50	YES	20:00	
			24SEP2011	YES	8:00	YES	20:00	
			25SEP2011	YES	8:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	26SEP2011	YES	7:50	YES	20:00	
			27SEP2011	YES	7:50	YES	20:00	
			28SEP2011	YES	7:50	YES	20:00	
			29SEP2011	YES	8:00	YES	20:00	
			30SEP2011	YES	8:00	YES	20:00	
			01OCT2011	YES	8:00	YES	20:00	
			02OCT2011	YES	8:00	YES	20:00	
			03OCT2011	YES	8:00	YES	20:00	
			04OCT2011	YES	8:00	YES	20:00	
			05OCT2011	YES	8:00	YES	20:00	
			06OCT2011	YES	8:00	YES	20:00	
			07OCT2011	YES	8:00	YES	20:00	
			08OCT2011	YES	8:00	YES	20:00	
			09OCT2011	YES	8:00	YES	20:00	
			10OCT2011	YES	8:00	YES	20:00	
			11OCT2011	YES	8:00	YES	20:00	
			12OCT2011	YES	8:00	YES	20:00	
			13OCT2011	YES	8:00	YES	20:00	
			14OCT2011	YES	8:00	YES	20:00	
			15OCT2011	YES	8:00	YES	20:00	
			16OCT2011	YES	8:00	YES	20:00	
			17OCT2011	YES	7:50	YES	20:00	
			18OCT2011	YES	7:50	YES	20:00	
			19OCT2011	YES	7:50	YES	20:00	
			20OCT2011	YES	7:45	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	083	17	21OCT2011	YES	7:45	YES	20:00	
			22OCT2011	YES	7:45	YES	20:00	
			23OCT2011	YES	8:00	YES	20:00	
			24OCT2011	YES	8:00	YES	20:00	
			25OCT2011	YES	8:00	YES	20:00	
			26OCT2011	YES	8:00	YES	20:00	
			27OCT2011	YES	8:00	YES	20:00	
			28OCT2011	YES	8:00	YES	20:00	
			29OCT2011	YES	8:00	YES	20:00	
			30OCT2011	YES	8:00	YES	20:00	
			31OCT2011	YES	8:00	YES	20:00	
			01NOV2011	YES	8:00	YES	20:00	
			02NOV2011	YES	7:45	YES	20:00	
			03NOV2011	YES	7:45	YES	20:00	
			04NOV2011	YES	7:50	YES	20:00	
			05NOV2011	YES	7:45	YES	20:00	
			06NOV2011	YES	7:45	YES	20:00	
			07NOV2011	YES	7:50	YES	20:10	
			08NOV2011	YES	7:50	YES	20:00	
			09NOV2011	YES				
	087	16		YES	7:15			
			30NOV2010	YES	8:00	YES	18:30	
			01DEC2010	YES	8:00	YES	18:30	
			02DEC2010	YES	8:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	03DEC2010	YES	7:30	YES	18:15	
			04DEC2010	YES	7:15	YES	18:30	
			05DEC2010	YES	7:30	YES	18:30	
			06DEC2010	YES	7:30	YES	18:15	
			07DEC2010	YES	7:00	YES	18:30	
			08DEC2010	YES	8:00		18:30	
			09DEC2010	YES	8:00	YES	18:15	
			10DEC2010	YES	7:15	YES	18:15	
			11DEC2010	YES	8:00	YES	18:45	
			12DEC2010	YES	8:00	YES	18:15	
			13DEC2010	YES	8:00	YES	18:15	
			14DEC2010	YES	7:15	YES	18:15	
			15DEC2010	YES	5:45	YES	18:15	
			16DEC2010	YES	8:00	YES	18:30	
			17DEC2010	YES	7:30	YES	18:30	
			18DEC2010	YES	8:00		18:15	
			19DEC2010	YES	7:45	YES	18:15	
			20DEC2010	YES	8:00	YES	18:30	
			21DEC2010	YES	8:00		18:15	
			22DEC2010	YES	8:00	YES	18:15	
			23DEC2010	YES	7:45	YES	18:15	
			24DEC2010	YES	8:30	YES	19:00	
			25DEC2010	YES	8:30	YES	19:00	
			26DEC2010	YES	7:30	YES	18:00	
			27DEC2010	YES	8:15	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	28DEC2010	YES	7:45			
			29DEC2010	YES	8:15	YES	18:15	
			30DEC2010	YES	8:15	YES	17:45	
			31DEC2010	YES	8:00	YES	18:00	
			01JAN2011	YES	8:30	YES	17:45	
			02JAN2011	YES	8:15	YES	19:45	
			03JAN2011	YES	8:15	YES	17:45	
			04JAN2011	YES	8:00	YES	19:00	
			05JAN2011	YES	8:00	YES	20:00	
			06JAN2011	YES	7:15	YES	18:00	
			07JAN2011	YES	8:15	YES	18:00	
			08JAN2011	YES	8:00	YES	18:00	
			09JAN2011	YES	8:15	YES	18:00	
			10JAN2011	YES	8:00	YES	17:45	
			11JAN2011	YES	7:15	YES	18:00	
			12JAN2011	YES	8:15	YES	18:00	
			13JAN2011	YES	8:30	YES	17:45	
			14JAN2011	YES	8:00	YES	18:00	
			15JAN2011	YES	8:00	YES	18:00	
			16JAN2011	YES	8:00	YES	18:00	
			17JAN2011	YES	8:00		17:45	
			18JAN2011	YES	7:30	YES	18:00	
			19JAN2011	YES	5:45	YES	18:00	
			20JAN2011	YES	7:30	YES	18:00	
			21JAN2011	YES	7:30	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	22JAN2011	YES	8:00	YES	18:00	
			23JAN2011	YES	8:30	YES	17:45	
			24JAN2011	YES	8:15	YES	17:45	
			25JAN2011	YES	7:15	YES	18:00	
			26JAN2011	YES	7:45	YES	17:30	
			27JAN2011	YES	6:00	YES	18:00	
			28JAN2011	YES	7:45	YES	17:45	
			29JAN2011	YES	7:15	YES	18:00	
			30JAN2011	YES	8:00	YES	18:00	
			31JAN2011	YES	7:30	YES	18:00	
			01FEB2011	YES	7:15	YES	18:00	
			02FEB2011	YES	6:00	YES	18:00	
			03FEB2011	YES	7:15	YES	18:00	
			04FEB2011	YES	8:00	YES	18:00	
			05FEB2011	YES	7:45	YES	18:00	
			06FEB2011	YES	8:15	YES	18:00	
			07FEB2011	YES	7:45	YES	18:00	
			08FEB2011	YES	6:00	YES	17:45	
			09FEB2011	YES	7:45	YES	17:45	
			10FEB2011	YES	6:15	YES	18:00	
			11FEB2011	YES	8:15	YES	18:00	
			12FEB2011	YES	8:00			
			13FEB2011	YES	8:15	YES	17:45	
			14FEB2011	YES	8:15	YES	18:00	
			15FEB2011	YES	6:15	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	16FEB2011	YES	7:45	YES	17:30	
			17FEB2011	YES	7:45			
			18FEB2011	YES	8:00	YES	18:00	
			19FEB2011	YES	8:15	YES	18:00	
			20FEB2011	YES	8:00	YES	18:00	
			21FEB2011	YES	7:15	YES	18:00	
			22FEB2011	YES	6:15	YES	18:00	
			23FEB2011	YES	6:15	YES	18:00	
			24FEB2011	YES	6:15	YES	18:00	
			25FEB2011	YES	7:15	YES	18:00	
			26FEB2011	YES	7:30	YES	18:00	
			27FEB2011	YES	8:00	YES	18:00	
			28FEB2011	YES	7:45	YES	17:45	
			01MAR2011	YES	6:15	YES	18:00	
			02MAR2011	YES	7:45	YES	18:00	
			03MAR2011	YES	6:00	YES	18:00	
			04MAR2011	YES	7:30	YES	17:45	
			05MAR2011	YES	6:15	YES	18:00	
			06MAR2011	YES	7:30	YES	17:45	
			07MAR2011	YES	7:30			
			08MAR2011	YES	6:00	YES	18:00	
			09MAR2011	YES	7:00	YES	18:30	
			10MAR2011	YES	6:15	YES	18:00	
			11MAR2011	YES	7:15	YES	18:00	
			12MAR2011	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	13MAR2011	YES	7:30	YES	17:45	
			14MAR2011	YES	7:45	YES	18:00	
			15MAR2011	YES	6:15	YES	17:45	
			16MAR2011	YES	7:30	YES	18:00	
			17MAR2011	YES	6:30	YES	18:00	
			18MAR2011	YES	7:30	YES	18:00	
			19MAR2011	YES	6:30	YES	18:00	
			20MAR2011	YES	8:00	YES	18:30	
			21MAR2011	YES	8:00	YES	18:00	
			22MAR2011	YES	6:15	YES	18:00	
			23MAR2011	YES	7:45	YES	17:30	
			24MAR2011	YES	6:15	YES	18:00	
			25MAR2011	YES	7:45	YES	18:15	
			26MAR2011	YES	7:15	YES	18:00	
			27MAR2011	YES	7:45	YES	18:00	
			28MAR2011	YES	8:15		18:00	
			29MAR2011	YES	6:15	YES	18:00	
			30MAR2011	YES	6:15	YES	18:00	
			31MAR2011	YES	6:15	YES	18:00	
			01APR2011	YES	7:30	YES	17:45	
			02APR2011	YES	6:30		18:00	
			03APR2011	YES	7:30	YES	18:00	
			04APR2011	YES	8:00	YES	18:00	
			05APR2011	YES	6:30	YES	18:00	
			06APR2011	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	07APR2011	YES	6:30			
			08APR2011	YES	7:30	YES	18:30	
			09APR2011	YES	7:30	YES	18:00	
			10APR2011	YES				
			11APR2011	YES	7:30		17:45	
			12APR2011	YES	6:15	YES	18:00	
			13APR2011	YES	7:30	YES	17:30	
			14APR2011	YES	6:15	YES	18:00	
			15APR2011	YES	7:30	YES	17:45	
			16APR2011	YES	7:30	YES	18:00	
			17APR2011	YES	8:00	YES	18:30	
			18APR2011	YES	7:30	YES	17:45	
			19APR2011	YES	6:15	YES	17:45	
			20APR2011	YES	7:45	YES	18:00	
			21APR2011	YES	6:15	YES	17:45	
			22APR2011	YES	7:30	YES	17:00	
			23APR2011	YES	8:15			
			24APR2011	YES	8:00	YES	18:00	
			25APR2011	YES	8:00	YES	18:00	
			26APR2011	YES	6:15	YES	18:00	
			27APR2011	YES	7:15	YES	18:00	
			28APR2011	YES	6:15	YES	18:00	
			29APR2011	YES	7:30	YES	18:00	
			30APR2011	YES	7:45	YES	18:00	
			01MAY2011	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	02MAY2011	YES	8:15	YES	18:00	
			03MAY2011	YES	6:15	YES	18:00	
			04MAY2011	YES	6:30	YES	18:00	
			05MAY2011	YES	6:15	YES	18:00	
			06MAY2011	YES	7:15	YES	18:15	
			07MAY2011		8:00	YES	18:00	
			08MAY2011	YES	8:15	YES	18:00	
			09MAY2011	YES	6:15	YES	17:45	
			10MAY2011	YES	6:30	YES	18:15	
			11MAY2011	YES	7:30	YES	18:00	
			12MAY2011	YES	6:15	YES	18:00	
			13MAY2011	YES	7:30	YES	18:30	
			14MAY2011	YES	7:30	YES	18:00	
			15MAY2011	YES	7:30	YES	18:00	
			16MAY2011	YES	6:30			
			17MAY2011	YES	6:15	YES	18:00	
			18MAY2011	YES	8:00	YES	18:00	
			19MAY2011	YES	6:15	YES	18:00	
			20MAY2011	YES	7:30	YES	18:00	
			21MAY2011	YES	7:45	YES	18:00	
			22MAY2011	YES	7:00	YES	18:00	
			23MAY2011	YES	8:15			
			24MAY2011	YES	6:00	YES	17:45	
			25MAY2011	YES	7:45	YES	18:00	
			26MAY2011	YES	6:15	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	27MAY2011	YES		YES	18:00	
			28MAY2011	YES	7:15	YES	18:00	
			29MAY2011	YES	7:00	YES	18:00	
			30MAY2011	YES	7:30	YES	17:45	
			31MAY2011	YES	8:00	YES	17:30	
			01JUN2011	YES	6:30	YES	18:00	
			02JUN2011	YES	8:00	YES	18:00	
			03JUN2011	YES	6:15	YES	18:00	
			04JUN2011	YES	8:30	YES	18:15	
			05JUN2011	YES	7:30	YES	18:00	
			06JUN2011	YES	7:15	YES	18:00	
			07JUN2011	YES	6:15	YES	18:00	
			08JUN2011	YES	6:30	YES	18:00	
			09JUN2011	YES	6:15	YES	17:45	
			10JUN2011	YES	7:00	YES	18:15	
			11JUN2011	YES	8:15	YES	18:00	
			12JUN2011	YES	8:15	YES	17:30	
			13JUN2011	YES	7:30	YES	18:00	
			14JUN2011	YES	6:30	YES	18:00	
			15JUN2011	YES	8:00	YES	18:30	
			16JUN2011	YES	6:15	YES	18:00	
			17JUN2011	YES	7:45	YES	18:15	
			18JUN2011	YES	7:30	YES	17:45	
			19JUN2011	YES	8:15	YES	19:15	
			20JUN2011	YES	8:15	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	21JUN2011	YES	6:15	YES	18:00	
			22JUN2011	YES	7:30	YES	18:00	
			23JUN2011	YES	6:15	YES	18:00	
			24JUN2011	YES	7:45	YES	18:00	
			25JUN2011	YES	6:30	YES	19:00	
			26JUN2011	YES	8:15	YES	18:00	
			27JUN2011	YES	7:45	YES	18:30	
			28JUN2011	YES	6:15	YES	18:00	
			29JUN2011	YES	7:45	YES	18:30	
			30JUN2011	YES	6:30	YES	18:00	
			01JUL2011	YES	7:30			
			02JUL2011	YES	7:30	YES	18:00	
			03JUL2011	YES	6:30	YES	18:00	
			04JUL2011	YES	8:00	YES	18:00	
			05JUL2011	YES	6:15	YES	17:45	
			06JUL2011	YES	8:15	YES	17:45	
			07JUL2011	YES	6:15	YES	18:00	
			08JUL2011	YES	7:30	YES	18:00	
			09JUL2011	YES	7:45	YES	18:00	
			10JUL2011	YES	7:45	YES	18:00	
			11JUL2011	YES	6:45	YES	17:45	
			12JUL2011	YES	6:15	YES	18:00	
			13JUL2011	YES	7:00	YES	18:15	
			14JUL2011	YES	6:15		18:00	
			15JUL2011	YES	7:00	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	16JUL2011	YES	7:30	YES	18:00	
			17JUL2011	YES	8:00	YES	18:00	
			18JUL2011	YES	7:45	YES	18:00	
			19JUL2011	YES	6:15	YES	18:00	
			20JUL2011	YES	6:15	YES	18:00	
			21JUL2011	YES	6:15	YES	18:00	
			22JUL2011	YES	8:00	YES	18:00	
			23JUL2011	YES	7:30	YES	18:00	
			24JUL2011	YES	7:30	YES	18:00	
			25JUL2011	YES	7:45	YES	18:00	
			26JUL2011	YES	6:15			
			27JUL2011	YES	8:00	YES	18:00	
			28JUL2011	YES	6:15	YES	18:15	
			29JUL2011	YES	7:45	YES	18:00	
			30JUL2011	YES	7:30	YES	18:00	
			31JUL2011	YES	8:30	YES	18:00	
			01AUG2011	YES	7:45	YES	18:00	
			02AUG2011	YES	6:15	YES	17:45	
			03AUG2011	YES	8:00	YES	18:00	
			04AUG2011	YES	6:15	YES	18:00	
			05AUG2011	YES	7:15	YES	18:00	
			06AUG2011	YES	7:15	YES	18:00	
			07AUG2011	YES	8:00	YES	18:30	
			08AUG2011	YES	8:00	YES	18:00	
			09AUG2011	YES	6:15	YES	18:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	11AUG2011	YES	6:15	YES	18:00	
			12AUG2011	YES	7:15	YES	18:00	
			13AUG2011	YES	8:30	YES		
			14AUG2011	YES	8:00	YES	18:15	
			15AUG2011	YES	7:45	YES	18:00	
			16AUG2011	YES	7:15		18:00	
			17AUG2011	YES	7:30		18:00	
			18AUG2011	YES	6:15	YES	18:00	
			19AUG2011	YES	8:30	YES	18:00	
			20AUG2011	YES	8:00	YES	18:45	
			21AUG2011	YES	8:15	YES	18:15	
			22AUG2011	YES	7:30	YES	18:15	
			23AUG2011	YES	6:30	YES	18:00	
			24AUG2011	YES	7:00	YES	18:00	
			25AUG2011	YES	6:30	YES	18:00	
			26AUG2011	YES	7:30	YES	18:00	
			27AUG2011	YES	8:30	YES	18:00	
			28AUG2011	YES	8:30	YES	18:15	
			29AUG2011	YES	7:30	YES	18:00	
			30AUG2011	YES	8:15	YES	17:45	
			31AUG2011	YES	6:30	YES	18:00	
			01SEP2011	YES	6:15	YES	18:00	
			02SEP2011	YES	7:15	YES	18:15	
			03SEP2011	YES	7:30	YES	18:00	
			04SEP2011	YES	8:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	05SEP2011	YES	7:15	YES	18:00	
			06SEP2011	YES	6:15	YES	18:00	
			07SEP2011	YES	8:00		18:00	
			08SEP2011		6:15	YES	18:00	
			09SEP2011	YES	7:30	YES	18:00	
			10SEP2011	YES	7:15	YES	18:00	
			11SEP2011	YES	7:30	YES	18:30	
			12SEP2011			YES	18:00	
			13SEP2011	YES	6:15	YES	18:15	
			14SEP2011	YES	7:45	YES	18:00	
			15SEP2011	YES	6:15	YES	18:15	
			16SEP2011	YES	7:45	YES	18:00	
			17SEP2011	YES	8:00	YES	18:00	
			18SEP2011	YES	7:30	YES	18:00	
			19SEP2011	YES	8:00	YES	17:45	
			20SEP2011	YES	6:30	YES	18:00	
			21SEP2011	YES	8:00	YES	17:30	
			22SEP2011	YES	6:15	YES	18:00	
			23SEP2011	YES	7:15	YES	18:00	
			24SEP2011	YES	8:15			
			25SEP2011	YES	7:45	YES	18:00	
			26SEP2011	YES	6:45	YES	18:00	
			27SEP2011	YES	6:15	YES	18:00	
			28SEP2011	YES	7:45	YES	18:00	
			29SEP2011	YES	6:15	YES	18:00	

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	30SEP2011	YES	7:30	YES	18:00	
			01OCT2011		7:30	YES	18:00	
			02OCT2011	YES	7:45	YES	18:00	
			03OCT2011	YES	8:00	YES	18:15	
			04OCT2011	YES	6:15	YES	17:30	
			05OCT2011	YES	8:30	YES	17:30	
			06OCT2011	YES	8:15	YES	17:30	
			07OCT2011	YES	8:00	YES	18:00	
			08OCT2011	YES	8:15			
			09OCT2011	YES	7:30	YES	18:00	
			10OCT2011	YES	7:45	YES	18:00	
			11OCT2011	YES	6:15	YES	18:45	
			12OCT2011	YES	6:30		18:00	
			13OCT2011	YES	6:30	YES	18:00	
			14OCT2011	YES	7:45	YES	17:45	
			15OCT2011	YES	7:30	YES	17:30	
			16OCT2011	YES	8:00	YES	17:15	
			17OCT2011	YES	7:30	YES	18:00	
			18OCT2011	YES	6:15	YES	18:15	
			19OCT2011	YES	7:30	YES	18:00	
			20OCT2011	YES	6:15	YES	18:00	
			21OCT2011	YES	8:00	YES	18:15	
			22OCT2011	YES	7:15	YES	18:00	
			23OCT2011	YES	8:00	YES	18:00	
			24OCT2011	YES	8:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	25OCT2011	YES	6:15	YES	18:00	
			26OCT2011	YES	8:15	YES	18:00	
			27OCT2011	YES	6:15	YES	17:30	
			28OCT2011	YES	8:30	YES	18:15	
			29OCT2011	YES	7:45	YES	17:45	
			30OCT2011	YES	7:15	YES	18:00	
			31OCT2011	YES	7:15		18:00	
			01NOV2011	YES	8:00	YES	18:15	
			02NOV2011	YES	8:15	YES	18:00	
			03NOV2011	YES	6:15	YES	18:00	
			04NOV2011	YES	8:15	YES	18:00	
			05NOV2011	YES	8:15	YES	18:00	
			06NOV2011	YES	8:00	YES	18:00	
			07NOV2011	YES	7:15			
			08NOV2011	YES	6:15	YES	18:00	
			09NOV2011	YES	6:15	YES	18:00	
			10NOV2011	YES	6:15	YES	18:00	
			11NOV2011	YES	7:15	YES	18:00	
			12NOV2011	YES	7:45	YES	18:00	
			13NOV2011	YES	8:00	YES	18:00	
			14NOV2011	YES	8:00	YES	18:00	
			15NOV2011	YES	6:30	YES	18:00	
			16NOV2011	YES	8:00	YES	18:00	
			17NOV2011	YES	6:15			
			18NOV2011	YES	8:30	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	087	16	19NOV2011		8:15	YES	18:00	
			20NOV2011	YES	8:30	YES	18:00	
			21NOV2011	YES	7:45	YES	18:00	
			22NOV2011	YES	6:30	YES	18:00	
			23NOV2011	YES	6:15	YES	18:00	
			24NOV2011	YES	6:15	YES	18:00	
			25NOV2011	YES	8:15	YES	18:00	
			26NOV2011	YES		YES	18:45	
			27NOV2011	YES	8:30	YES	18:00	
			28NOV2011	YES	6:30			
	089	5	17NOV2010			YES	21:30	
			18NOV2010	YES	8:00	YES	21:00	
			19NOV2010	YES	7:30	YES	20:00	
			20NOV2010	YES	7:45	YES	20:20	
			21NOV2010	YES	7:55	YES	20:00	
			22NOV2010	YES	7:15	YES	20:00	
			23NOV2010	YES	8:10	YES	20:40	
			24NOV2010	YES	7:55	YES	20:20	
			25NOV2010	YES	7:55	YES	20:00	
			26NOV2010	YES	7:55	YES	20:10	
			27NOV2010	YES	8:00	YES	19:10	
			28NOV2010	YES	8:05	YES	20:00	
			29NOV2010	YES	8:05	YES	20:00	
			30NOV2010	YES	7:10	YES	20:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	01DEC2010	YES	8:05	YES	20:00	
			02DEC2010	YES	7:50	YES	21:05	
			03DEC2010	YES	7:55	YES	20:00	
			04DEC2010	YES	8:00	YES	19:55	
			05DEC2010	YES	8:05	YES	20:00	
			06DEC2010	YES	7:50	YES	20:00	
			07DEC2010	YES	7:55	YES	20:05	
			08DEC2010	YES	7:50	YES	21:25	
			09DEC2010	YES	8:10	YES	20:35	
			10DEC2010	YES	8:15	YES	20:05	
			11DEC2010	YES	8:10	YES	20:35	
			12DEC2010	YES	8:15	YES	20:40	
			13DEC2010	YES	8:00	YES	20:45	
			14DEC2010	YES	6:45			
			14DEC2010			YES	20:00	
			15DEC2010	YES	8:00	YES	20:45	
			16DEC2010	YES	7:55	YES	20:35	
			17DEC2010	YES	8:00	YES	20:10	
			18DEC2010	YES	8:05	YES	20:45	
			19DEC2010	YES	8:00	YES	20:35	
			20DEC2010	YES	7:45	YES	19:55	
			21DEC2010	YES	8:00	YES	20:20	
			22DEC2010	YES	7:55	YES	20:25	
			23DEC2010	YES	7:15	YES	20:15	
			24DEC2010	YES	8:20	YES	22:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	25DEC2010	YES	8:20	YES	20:15	
			26DEC2010	YES	8:00	YES	20:10	
			27DEC2010	YES	8:05	YES	20:20	
			28DEC2010	YES	8:15	YES	20:35	
			29DEC2010	YES	8:00	YES	20:15	
			30DEC2010	YES	8:10	YES	20:05	
			31DEC2010	YES	8:05	YES	20:30	
			01JAN2011	YES	8:30	YES	20:00	
			02JAN2011	YES	8:10	YES	20:15	
			03JAN2011	YES	8:20	YES	20:20	
			04JAN2011	YES	8:05	YES	20:15	
			05JAN2011	YES	7:55	YES	20:35	
			06JAN2011	YES	8:10	YES	20:15	17:20 umgekippt, Bewusstsein verloren
			07JAN2011	YES	7:55	YES	20:20	
			08JAN2011	YES	8:10	YES	20:05	
			09JAN2011	YES	8:40	YES	20:40	
			10JAN2011	YES	8:00	YES	20:45	
			11JAN2011	YES	8:15	YES	20:15	
			12JAN2011	YES	8:10	YES	20:25	
			13JAN2011	YES	8:15	YES	20:15	
			14JAN2011	YES	8:20	YES	20:10	
			15JAN2011	YES	8:15	YES	21:05	
			16JAN2011	YES	8:25	YES	20:20	
			17JAN2011	YES	8:20	YES	20:15	
			18JAN2011	YES	8:20	YES	20:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	19JAN2011	YES	7:30	YES	20:15	
			20JAN2011	YES	8:10	YES	20:05	
			21JAN2011	YES	8:15	YES	20:05	
			22JAN2011	YES	8:20	YES	20:00	
			23JAN2011	YES	8:40	YES	20:50	
			24JAN2011	YES	8:05	YES	20:15	
			25JAN2011	YES	8:00	YES	20:00	
			26JAN2011	YES	8:10	YES	21:20	
			27JAN2011	YES	7:35	YES	19:08	
			28JAN2011	YES	8:00	YES	18:05	
			29JAN2011	YES	7:55	YES	18:00	
			30JAN2011	YES	8:00	YES	18:10	
			31JAN2011		8:00	YES	18:00	
			01FEB2011	YES	8:05	YES	17:55	
			02FEB2011	YES	7:50	YES	20:05	
			03FEB2011	YES	8:00	YES	20:20	
			04FEB2011	YES	8:05	YES	20:00	
			05FEB2011	YES	7:55	YES	20:15	
			06FEB2011	YES	8:00	YES	20:00	
			07FEB2011	YES	8:05			
			02MAY2011			YES	20:10	
			03MAY2011	YES	7:30	YES	20:35	
			04MAY2011	YES	8:00	YES	20:45	
			05MAY2011	YES	8:15	YES	20:10	
			06MAY2011	YES	7:30	YES	20:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	07MAY2011	YES	8:05	YES	21:10	
			08MAY2011	YES	8:15	YES	20:15	
			09MAY2011	YES	7:55	YES	20:45	
			10MAY2011	YES	7:30	YES	20:15	
			11MAY2011	YES	8:00	YES	20:40	
			12MAY2011	YES	8:00	YES	20:15	
			13MAY2011	YES	7:35	YES	20:25	
			14MAY2011	YES	8:15	YES	20:40	
			15MAY2011	YES	8:40	YES	20:10	
			16MAY2011	YES	8:10	YES	20:00	
			17MAY2011	YES	7:35	YES	20:35	
			18MAY2011	YES	8:00	YES	20:00	
			19MAY2011	YES	8:15	YES	20:20	
			20MAY2011	YES	7:35	YES	20:20	
			21MAY2011	YES	8:05	YES	20:50	
			22MAY2011	YES	8:00	YES	20:10	
			23MAY2011	YES	8:00	YES	20:00	
			24MAY2011	YES	7:35	YES	20:10	
			25MAY2011	YES	8:10	YES	20:25	
			26MAY2011	YES	8:05	YES	21:10	
			27MAY2011	YES	7:35	YES	20:20	
			28MAY2011	YES	8:10		20:35	
			29MAY2011	YES	8:05		20:10	
			30MAY2011	YES	8:00	YES	20:15	
			31MAY2011	YES	7:35	YES	20:20	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	01JUN2011	YES	8:10	YES	20:15	
			02JUN2011	YES	8:10	YES	22:15	
			03JUN2011	YES	7:35	YES	20:25	
			04JUN2011	YES	8:10	YES	20:10	
			05JUN2011	YES	8:05	YES	21:10	
			06JUN2011	YES	8:00	YES	20:15	
			07JUN2011	YES	7:35	YES	20:15	
			08JUN2011	YES	8:05	YES	20:30	
			09JUN2011	YES	8:00	YES	21:10	
			10JUN2011	YES	7:30	YES	20:15	
			11JUN2011	YES	8:05	YES	20:30	
			12JUN2011	YES	8:10	YES	21:20	
			13JUN2011	YES	8:20	YES	20:25	
			14JUN2011	YES	7:35	YES	21:10	
			15JUN2011	YES	8:00	YES	20:05	
			16JUN2011	YES	8:00	YES	20:00	
			17JUN2011	YES	7:30	YES	20:15	
			18JUN2011	YES	8:20	YES	20:00	
			19JUN2011	YES	8:05	YES	20:10	
			20JUN2011	YES	8:15	YES	20:45	
			21JUN2011	YES	7:30	YES	20:25	
			22JUN2011	YES	8:10	YES	20:05	
			23JUN2011	YES	8:15	YES	20:40	
			24JUN2011	YES	7:30	YES	20:15	
			25JUN2011	YES	8:05	YES	21:50	

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	26JUN2011	YES	8:10	YES	20:10	
			27JUN2011	YES	8:20		20:05	
			28JUN2011	YES	7:30	YES	20:15	
			29JUN2011	YES	8:00	YES	20:10	
			30JUN2011	YES	8:05	YES	20:15	
			01JUL2011	YES	7:30	YES	20:10	
			03JUL2011	YES	8:00	YES	20:30	
			04JUL2011	YES	8:10	YES	20:50	
			05JUL2011	YES	7:30	YES	20:00	
			06JUL2011	YES	8:10	YES	20:05	
			07JUL2011	YES	8:15	YES	20:15	
			08JUL2011	YES	7:30	YES	21:25	
			09JUL2011	YES	8:30	YES	20:10	
			10JUL2011	YES	8:10	YES	20:00	
			11JUL2011	YES	8:20	YES	20:05	
			12JUL2011	YES	8:00	YES	20:45	
			13JUL2011	YES	7:30	YES	20:15	
			14JUL2011	YES	8:00	YES	20:40	
			15JUL2011	YES	7:30	YES	20:00	
			16JUL2011	YES	8:10	YES	21:35	
			17JUL2011	YES	8:00	YES	20:00	
			18JUL2011	YES	8:05	YES	20:00	
			19JUL2011	YES	7:30	YES	20:15	
			20JUL2011	YES	8:10	YES	20:25	
			21JUL2011	YES	8:00	YES	20:05	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	22JUL2011	YES	7:30	YES	20:10	
			23JUL2011	YES	8:00	YES	20:40	
			24JUL2011	YES	8:15	YES	20:10	
			25JUL2011	YES	7:50			
			25JUL2011			YES	20:10	
			26JUL2011	YES	7:30	YES	20:40	
			27JUL2011	YES	8:00	YES	20:30	
			28JUL2011		8:05	YES	20:15	
			29JUL2011	YES	7:30	YES	20:00	
			30JUL2011	YES	8:00	YES	20:50	
			31JUL2011	YES	8:25	YES	21:30	
			01AUG2011	YES	8:00	YES	20:10	
			02AUG2011	YES	7:35	YES	20:00	
			03AUG2011	YES	8:05	YES	20:15	
			04AUG2011	YES	8:00	YES	20:00	
			05AUG2011	YES	7:35	YES	20:10	
			06AUG2011	YES	8:05	YES	20:35	
			07AUG2011	YES	8:05	YES	20:10	
			08AUG2011	YES	8:00	YES	20:20	
			09AUG2011	YES	7:35	YES	20:15	
			10AUG2011	YES	7:35	YES	21:20	
			11AUG2011	YES	8:05	YES	20:00	
			12AUG2011	YES	7:35	YES	20:20	
			13AUG2011	YES	8:05	YES	20:00	
			14AUG2011	YES	8:00	YES	20:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	15AUG2011	YES	8:05	YES	20:35	
			16AUG2011	YES	7:35	YES	21:00	
			17AUG2011	YES	8:00	YES	20:05	
			18AUG2011	YES	8:00	YES	20:10	
			19AUG2011	YES	7:35	YES	20:30	
			20AUG2011	YES	8:00	YES	20:00	
			21AUG2011	YES	8:05	YES	20:50	
			22AUG2011	YES	8:00	YES	20:15	
			23AUG2011	YES	7:35		21:05	
			24AUG2011	YES	8:05	YES	20:05	
			25AUG2011	YES	8:00	YES	20:25	
			26AUG2011	YES	7:35	YES	20:00	
			27AUG2011	YES	8:10	YES	20:15	
			28AUG2011	YES	8:05	YES	20:00	
			29AUG2011	YES	8:00	YES	20:00	
			30AUG2011	YES	7:40	YES	21:05	
			31AUG2011	YES	8:20	YES	20:20	
			01SEP2011	YES	8:05	YES	20:15	
			02SEP2011	YES	7:35	YES	20:20	
			03SEP2011	YES	8:30	YES	20:10	
			04SEP2011	YES	8:05	YES	20:00	
			05SEP2011	YES	8:00	YES	20:05	
			06SEP2011	YES	7:35	YES	20:20	
			07SEP2011	YES	8:05	YES	20:15	
			08SEP2011	YES	8:05	YES	20:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	09SEP2011	YES	7:35	YES	21:50	
			10SEP2011	YES	8:30		20:15	
			11SEP2011	YES	8:05	YES	20:00	
			12SEP2011	YES	8:00	YES	20:10	
			13SEP2011	YES	7:35	YES	20:05	
			14SEP2011	YES	8:05	YES	20:20	
			15SEP2011	YES	8:00	YES	20:10	
			16SEP2011	YES	7:35	YES	20:00	
			17SEP2011	YES	8:15	YES	20:05	
			18SEP2011	YES	8:20	YES	20:15	
			19SEP2011	YES	8:00	YES	20:00	
			20SEP2011	YES	7:35	YES	20:00	
			21SEP2011	YES	8:00	YES	20:20	
			22SEP2011	YES	8:10	YES	20:00	
			23SEP2011	YES	7:30	YES	20:15	
			24SEP2011	YES	8:00	YES	20:05	
			25SEP2011	YES	8:20	YES	20:10	
			26SEP2011	YES	8:10	YES	20:05	
			27SEP2011	YES	7:30	YES	20:10	
			28SEP2011	YES	7:40	YES	20:00	
			29SEP2011	YES	8:10	YES	20:15	
			30SEP2011	YES	7:30	YES	20:20	
			01OCT2011	YES	8:05	YES	20:05	
			02OCT2011	YES	8:30	YES	20:25	
			03OCT2011	YES	8:25	YES	20:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	04OCT2011	YES	7:35	YES	20:05	
			05OCT2011	YES	8:10	YES	20:25	
			06OCT2011	YES	8:00	YES	20:10	
			07OCT2011	YES	7:30	YES	20:00	
			08OCT2011	YES	8:05	YES	20:05	
			09OCT2011	YES	8:25	YES	20:20	
			10OCT2011	YES	8:00	YES	20:05	
			11OCT2011	YES	7:35	YES	20:00	
			12OCT2011	YES	8:10	YES	20:45	
			13OCT2011	YES	8:00	YES	20:30	
			14OCT2011	YES	7:35	YES	20:00	
			15OCT2011	YES	8:05	YES	20:10	
			16OCT2011	YES	8:00	YES	20:15	
			17OCT2011	YES	8:15	YES	20:10	
			18OCT2011	YES	7:30	YES	20:05	
			19OCT2011	YES	8:00	YES	20:45	
			20OCT2011	YES	8:10	YES	20:15	
			21OCT2011	YES	7:30	YES	20:20	
			22OCT2011	YES	8:00	YES	20:10	
			23OCT2011	YES	8:20	YES	20:05	
			24OCT2011	YES	8:00	YES	20:00	
			25OCT2011	YES	7:35	YES	20:10	
			26OCT2011	YES	8:05	YES	20:10	
			27OCT2011	YES	8:00	YES	20:15	
			28OCT2011	YES	7:30	YES	20:05	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	089	5	29OCT2011	YES	8:05	YES	20:15	
			30OCT2011	YES	8:05	YES	20:05	
			31OCT2011	YES	8:00	YES	20:10	
			01NOV2011	YES	7:35	YES	20:10	
			02NOV2011	YES	8:05	YES	20:20	
			03NOV2011	YES	8:00	YES	20:05	
			04NOV2011	YES	7:35	YES	20:15	
			05NOV2011	YES	8:05	YES	20:00	
			06NOV2011	YES	8:20	YES	20:30	
			07NOV2011	YES	8:00	YES	20:10	
			08NOV2011	YES	7:35	YES	21:10	
			09NOV2011	YES	7:50	YES	20:00	
			10NOV2011	YES	8:05	YES	20:20	
			11NOV2011	YES	7:35	YES	20:00	
			12NOV2011	YES	8:05	YES	20:10	
			13NOV2011	YES	8:10	YES	20:45	
			14NOV2011	YES	7:45			
	093	17	02DEC2010	YES	7:00	YES	19:00	
			03DEC2010	YES	7:00	YES	19:00	
			04DEC2010	YES	7:00	YES	19:30	
			05DEC2010	YES	7:00	YES	19:30	
			06DEC2010	YES	7:00	YES	19:00	
			07DEC2010	YES	7:00	YES	19:00	
			08DEC2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	09DEC2010	YES	7:00	YES	19:00	
			10DEC2010	YES	7:00	YES	19:00	
			11DEC2010	YES	7:00	YES	19:00	
			12DEC2010	YES	7:00	YES	19:00	
			13DEC2010	YES	7:10	YES	19:30	
			14DEC2010	YES	7:10	YES	19:30	
			15DEC2010	YES	7:00	YES	19:00	
			16DEC2010	YES	7:00	YES	19:00	
			17DEC2010	YES	7:10	YES	19:30	
			18DEC2010	YES	7:00	YES	19:00	
			19DEC2010	YES	7:00	YES	19:00	
			20DEC2010	YES	7:00	YES	19:00	
			21DEC2010	YES	7:10	YES	19:30	
			22DEC2010	YES	7:10	YES	19:30	
			23DEC2010	YES	7:10	YES	19:00	
			24DEC2010	YES	7:10	YES	19:30	
			25DEC2010	YES	7:10	YES	19:30	
			26DEC2010	YES	7:10	YES	19:30	
			27DEC2010	YES	7:00	YES	19:30	
			28DEC2010	YES	7:10	YES	19:15	
			29DEC2010	YES	7:30	YES	19:15	
			30DEC2010	YES	7:30	YES	19:20	
			31DEC2010	YES	7:30	YES	19:30	
			01JAN2011	YES	7:30	YES	19:20	
			02JAN2011	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	03JAN2011	YES	7:00	YES	19:00	
			04JAN2011	YES	7:00	YES	19:00	
			05JAN2011	YES	7:00			
			05JAN2011	YES		YES	19:00	
			06JAN2011	YES	7:10	YES	19:30	
			07JAN2011		7:10		19:30	
			08JAN2011		7:00		19:25	
			09JAN2011		7:00		19:25	
			10JAN2011		7:00		19:30	
			11JAN2011		7:10		19:30	
			12JAN2011		7:10		19:30	
			13JAN2011		7:10		19:15	
			14JAN2011	YES	7:00		19:30	
			15JAN2011		7:10		19:30	
			16JAN2011		7:15		19:35	
			17JAN2011		7:15		19:40	
			18JAN2011		7:15		19:40	
			19JAN2011		7:15		19:30	
			20JAN2011		7:15		19:30	
			21JAN2011		7:15		19:30	
			22JAN2011		7:15		19:30	
			23JAN2011		7:10		19:30	
			24JAN2011		7:10		19:30	
			25JAN2011		7:10		19:40	
			26JAN2011		7:15		19:40	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	27JAN2011		7:10		19:30	
			28JAN2011		7:15		19:17	
			29JAN2011		7:15		19:30	
			30JAN2011		7:15		19:30	
			31JAN2011		7:15		19:38	
			01FEB2011		7:10		19:30	
			02FEB2011		7:15		19:30	
			03FEB2011		7:15		19:35	
			04FEB2011		7:15		19:30	
			05FEB2011		7:10		19:30	
			06FEB2011		7:10		19:15	
			07FEB2011		7:10		19:30	
			08FEB2011		7:10		19:28	
			09FEB2011		7:10		17:20	
			10FEB2011		7:15		19:30	
			11FEB2011		7:15		19:30	
			12FEB2011		7:10		19:00	
			13FEB2011		7:00		19:00	
			14FEB2011		7:00		19:00	
			15FEB2011		7:00		19:00	
			16FEB2011		7:10		19:30	
			17FEB2011		7:10		19:30	
			18FEB2011		7:00		19:30	
			19FEB2011		7:00		19:30	
			20FEB2011		7:00		19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	21FEB2011		7:00		19:30	
			22FEB2011		7:30		19:30	
			23FEB2011		7:30		19:30	
			24FEB2011		7:00		19:30	
			25FEB2011	YES	7:00			
			25FEB2011			YES	19:00	
			26FEB2011	YES	7:45	YES	19:30	
			27FEB2011	YES	7:00	YES	19:00	
			28FEB2011	YES	7:30	YES	19:50	
			01MAR2011	YES	8:00	YES	19:00	
			02MAR2011	YES	8:00	YES	19:00	
			03MAR2011	YES	8:00	YES	19:00	
			04MAR2011	YES	8:00	YES	19:00	
			05MAR2011	YES	8:00	YES	20:00	
			06MAR2011	YES	8:00	YES	19:30	
			07MAR2011	YES	8:10	YES	19:30	
			08MAR2011	YES	8:10	YES	19:45	
			09MAR2011	YES	8:30	YES	19:45	
			10MAR2011	YES	8:15	YES	19:30	
			11MAR2011	YES	8:00	YES	19:30	
			12MAR2011	YES	8:00	YES	19:30	
			13MAR2011	YES	8:00	YES	19:00	
			14MAR2011	YES	8:00	YES	19:30	
			15MAR2011	YES	8:00	YES	19:30	
			16MAR2011	YES	8:00	YES	19:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	17MAR2011	YES	8:00	YES	19:15	
			18MAR2011	YES	8:15	YES	19:15	
			19MAR2011	YES	8:15	YES	19:30	
			20MAR2011	YES	8:15	YES	19:15	
			21MAR2011	YES	8:20	YES	19:15	
			22MAR2011	YES	8:00	YES	19:30	
			23MAR2011	YES	8:00	YES	19:00	
			24MAR2011	YES	8:00	YES	19:30	
			25MAR2011	YES	8:00	YES	19:30	
			26MAR2011	YES	8:15	YES	19:15	
			27MAR2011	YES	8:30	YES	20:00	
			28MAR2011	YES	8:15	YES	19:30	
			29MAR2011	YES	8:25	YES	19:50	
			30MAR2011	YES	8:00	YES	20:00	
			31MAR2011	YES	8:00	YES	20:00	
			01APR2011	YES	8:00	YES	20:00	
			02APR2011	YES	8:10	YES	20:10	
			03APR2011	YES	8:00	YES	20:00	
			04APR2011	YES	8:00	YES	20:00	
			05APR2011	YES	8:00	YES	20:10	
			06APR2011	YES	8:00	YES	20:10	
			07APR2011	YES	8:00	YES	20:15	
			08APR2011	YES	8:10	YES	19:10	
			09APR2011	YES	8:00	YES	19:00	
			10APR2011	YES	8:10	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	11APR2011	YES	8:15	YES	19:30	
			12APR2011	YES	8:15	YES	19:30	
			13APR2011	YES	8:15	YES	19:30	
			14APR2011	YES	8:15	YES	19:30	
			15APR2011	YES	8:15	YES	19:30	
			16APR2011	YES	8:14	YES	19:45	
			17APR2011	YES	8:20	YES	19:45	
			18APR2011	YES	8:20	YES	18:10	
			19APR2011	YES	7:15	YES	19:30	
			20APR2011	YES	7:30	YES	19:30	
			21APR2011	YES	7:30	YES	20:00	
			22APR2011	YES	7:30	YES	20:00	
			23APR2011	YES	7:30	YES	20:00	
			24APR2011	YES	7:40	YES	20:10	
			25APR2011	YES	7:40	YES	20:10	
			26APR2011	YES	7:40	YES	20:00	
			27APR2011	YES	7:45	YES	20:00	
			28APR2011	YES	7:15	YES	20:00	
			29APR2011	YES	7:15	YES	19:00	
			30APR2011	YES	7:15	YES	19:00	
			01MAY2011	YES	7:30	YES	19:00	
			02MAY2011	YES	7:30	YES	19:00	
			03MAY2011	YES	7:30	YES	19:00	
			04MAY2011	YES	7:30			vergessen
			05MAY2011	YES	7:30	YES	20:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	06MAY2011	YES	7:30	YES	20:00	
			07MAY2011	YES	7:00	YES	19:00	
			08MAY2011	YES	7:00	YES	19:00	
			09MAY2011	YES	7:00	YES	19:00	
			10MAY2011	YES	7:00	YES	19:00	
			11MAY2011	YES	7:00	YES	19:00	
			12MAY2011	YES	7:00	YES	19:00	
			13MAY2011	YES	7:00	YES	19:00	
			14MAY2011	YES	7:00	YES	19:00	
			15MAY2011	YES	7:00	YES	19:00	
			16MAY2011	YES	7:00	YES	20:00	
			17MAY2011	YES	7:00	YES	20:00	
			18MAY2011	YES	7:00	YES	19:30	
			19MAY2011	YES	7:00			
			20MAY2011	YES	7:30	YES	19:30	
			21MAY2011	YES	7:00	YES	19:30	
			22MAY2011	YES	7:00	YES	19:30	
			23MAY2011			YES	19:00	
			23MAY2011	YES	7:00			
			24MAY2011	YES	7:30	YES	19:00	
			25MAY2011	YES	7:30	YES	19:00	
			26MAY2011	YES	7:30	YES	19:00	
			27MAY2011	YES	7:40	YES	19:00	
			28MAY2011	YES	7:45	YES	19:00	
			29MAY2011	YES	7:40	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	30MAY2011	YES	7:30	YES	19:00	
			31MAY2011	YES	7:30	YES	19:00	
			01JUN2011	YES	7:20	YES	19:00	
			02JUN2011	YES	7:20	YES	19:00	
			03JUN2011	YES	7:20	YES	19:00	
			04JUN2011	YES	7:30	YES	19:00	
			05JUN2011	YES	7:30	YES	19:00	
			06JUN2011	YES	7:30	YES	19:00	
			07JUN2011	YES	7:30	YES	19:00	
			08JUN2011	YES	7:30	YES	19:00	
			09JUN2011	YES	7:30	YES	19:00	
			10JUN2011	YES	8:00	YES	19:30	
			11JUN2011	YES	8:00	YES	19:30	
			12JUN2011	YES	7:30	YES	19:45	
			13JUN2011	YES	7:45	YES	19:30	
			14JUN2011	YES	7:45	YES	19:30	
			15JUN2011	YES	7:30	YES	19:30	
			16JUN2011	YES	7:45	YES	19:30	
			17JUN2011	YES	7:30	YES	19:30	
			18JUN2011	YES	7:30	YES	19:30	
			19JUN2011	YES	7:30	YES	19:30	
			20JUN2011	YES	7:30	YES	19:30	
			21JUN2011	YES	7:30	YES	19:30	
			22JUN2011	YES	7:30	YES	19:30	
			23JUN2011	YES	7:30	YES	19:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	24JUN2011	YES	7:30	YES	19:30	
			25JUN2011	YES	7:30	YES	19:30	
			26JUN2011	YES	7:30	YES	19:30	
			27JUN2011	YES	7:30	YES	19:30	
			28JUN2011	YES	7:30	YES	19:30	
			29JUN2011	YES	7:30	YES	19:30	
			30JUN2011	YES	7:30	YES	19:30	
			01JUL2011	YES	7:30	YES	19:30	
			02JUL2011	YES	7:30	YES	19:30	
			03JUL2011	YES	7:30	YES	19:30	
			04JUL2011	YES	7:30	YES	19:30	
			05JUL2011	YES	7:30	YES	19:30	
			06JUL2011	YES	7:30	YES	19:30	
			07JUL2011	YES	7:30	YES	20:00	
			08JUL2011	YES	7:30	YES	20:00	
			09JUL2011	YES	7:30	YES	19:45	
			10JUL2011	YES	7:30	YES	19:45	
			11JUL2011	YES	7:30	YES	19:50	
			12JUL2011	YES	7:30	YES	19:30	
			13JUL2011	YES	7:30	YES	19:30	
			14JUL2011	YES	7:36	YES	19:30	
			15JUL2011	YES	7:45	YES	19:15	
			16JUL2011	YES	7:30	YES	19:30	
			17JUL2011	YES	7:30	YES	19:45	
			18JUL2011	YES	7:30	YES	19:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	19JUL2011	YES	7:30	YES	19:45	
			20JUL2011	YES	7:30	YES	19:45	
			21JUL2011	YES	7:30	YES	19:30	
			22JUL2011	YES	7:30	YES	19:30	
			23JUL2011	YES	7:30	YES	19:30	
			24JUL2011	YES	7:30	YES	19:30	
			25JUL2011	YES	7:30	YES	18:30	
			26JUL2011	YES	7:30	YES	19:30	
			27JUL2011	YES	7:30	YES	19:00	
			28JUL2011	YES	7:30	YES	18:45	
			29JUL2011	YES	7:30	YES	18:45	
			30JUL2011	YES	7:30	YES	19:30	
			31JUL2011	YES	7:30	YES	19:30	
			01AUG2011	YES	7:30	YES	19:30	
			02AUG2011	YES	7:30	YES	19:30	
			03AUG2011	YES	7:30	YES	19:30	
			04AUG2011	YES	7:30	YES	19:30	
			05AUG2011	YES	7:30	YES	19:30	
			06AUG2011	YES	7:30	YES	19:30	
			07AUG2011	YES	7:30	YES	19:45	
			08AUG2011	YES	7:30	YES	19:45	
			09AUG2011	YES	7:30	YES	19:30	
			10AUG2011	YES	7:30	YES	19:30	
			11AUG2011	YES	7:30	YES	19:30	
			12AUG2011	YES	7:30	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	13AUG2011	YES	7:30	YES	19:30	
			14AUG2011	YES	7:30	YES	19:30	
			15AUG2011	YES	7:30	YES	19:30	
			16AUG2011	YES				
			16AUG2011			YES	19:00	
			17AUG2011	YES	9:00	YES	20:30	
			18AUG2011	YES	8:00	YES	20:00	
			19AUG2011	YES	7:00	YES	19:00	
			20AUG2011	YES	7:05	YES	19:00	
			21AUG2011	YES	7:05	YES	19:00	
			22AUG2011	YES	7:10	YES	19:00	
			23AUG2011	YES	7:10	YES	19:00	
			24AUG2011	YES	7:10	YES	19:00	
			25AUG2011	YES	7:00	YES	19:00	
			26AUG2011	YES	7:05	YES	19:03	
			27AUG2011	YES	7:05	YES	19:00	
			28AUG2011	YES	7:10	YES	19:00	
			29AUG2011	YES	7:10	YES	19:00	
			30AUG2011	YES	7:10	YES	19:00	
			31AUG2011	YES	7:15	YES	19:00	
			01SEP2011	YES	7:15	YES	19:00	
			02SEP2011	YES	7:10	YES	19:00	
			03SEP2011	YES	7:00	YES	19:00	
			04SEP2011	YES	7:15	YES	19:10	
			05SEP2011	YES	7:15	YES	19:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	06SEP2011	YES	7:00	YES	19:00	
			07SEP2011	YES	7:00	YES	19:00	
			08SEP2011	YES	7:15	YES	19:30	
			09SEP2011	YES	7:15	YES	19:30	
			10SEP2011	YES	7:15	YES	19:30	
			11SEP2011	YES	7:15	YES	19:30	
			12SEP2011	YES	7:30	YES	19:15	
			13SEP2011	YES	7:30	YES	19:15	
			14SEP2011	YES	7:30	YES	19:20	
			15SEP2011	YES	7:30	YES	19:20	
			16SEP2011	YES	7:30	YES	19:20	
			17SEP2011	YES	7:30	YES	19:30	
			18SEP2011	YES	7:20	YES	19:30	
			19SEP2011	YES	7:30	YES	19:00	
			20SEP2011	YES	7:00	YES	19:15	
			21SEP2011	YES	7:30	YES	19:00	
			22SEP2011	YES	7:30	YES	19:00	
			23SEP2011	YES	7:30	YES	19:00	
			24SEP2011	YES	7:30	YES	19:00	
			25SEP2011	YES	7:30	YES	19:00	
			26SEP2011	YES	7:30	YES	19:00	
			27SEP2011	YES	7:30	YES	19:00	
			28SEP2011	YES	7:30	YES	19:00	
			29SEP2011	YES	7:30	YES	19:00	
			30SEP2011	YES	7:30	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	01OCT2011	YES	7:30	YES	19:30	
			02OCT2011	YES	7:35	YES	19:30	
			03OCT2011	YES	7:40	YES	19:30	
			04OCT2011	YES	7:40	YES	19:30	
			05OCT2011	YES	7:30	YES	19:21	
			06OCT2011	YES	7:35	YES	19:20	
			07OCT2011	YES	7:40	YES	19:20	
			08OCT2011	YES	7:40	YES	19:30	
			09OCT2011	YES	7:30	YES	19:30	
			10OCT2011	YES	7:30	YES	19:40	
			11OCT2011	YES	7:30	YES	19:40	
			12OCT2011	YES	7:30	YES	19:40	
			13OCT2011	YES	7:30	YES	19:30	
			14OCT2011	YES	7:50	YES	19:45	
			15OCT2011	YES	7:50	YES	19:55	
			16OCT2011	YES	7:50	YES	19:45	
			17OCT2011	YES	7:00	YES	19:45	
			18OCT2011	YES	7:30	YES	19:20	
			19OCT2011	YES	7:45	YES	19:30	
			20OCT2011	YES	7:45	YES	19:45	
			21OCT2011	YES	7:50	YES	19:40	
			22OCT2011	YES	7:45	YES	19:30	
			23OCT2011	YES	7:30	YES	19:30	
			24OCT2011	YES	7:30	YES	19:30	
			25OCT2011	YES	7:45	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	26OCT2011	YES	7:45	YES	19:45	
			27OCT2011	YES	7:30	YES	19:30	
			28OCT2011	YES	7:45	YES	19:31	
			29OCT2011	YES	7:35	YES	19:35	
			30OCT2011	YES	7:50	YES	19:50	
			31OCT2011	YES	7:50	YES	19:30	
			01NOV2011	YES	7:50	YES	19:50	
			02NOV2011	YES	7:35	YES	19:30	
			03NOV2011	YES	7:50	YES	19:45	
			04NOV2011	YES	7:50	YES	19:50	
			05NOV2011	YES	7:30	YES	19:20	
			06NOV2011	YES	7:40	YES	19:10	
			07NOV2011	YES	7:40	YES	19:30	
			08NOV2011	YES	7:30	YES	19:30	
			09NOV2011	YES	7:30	YES	19:40	
			10NOV2011	YES	7:40	YES	19:40	
			11NOV2011	YES	7:35	YES	19:50	
			12NOV2011	YES	7:50	YES	19:50	
			13NOV2011	YES	7:50	YES	19:30	
			14NOV2011	YES	7:30	YES	19:15	
			15NOV2011	YES	7:30	YES	19:30	
			16NOV2011	YES	7:20	YES	19:30	
			17NOV2011	YES	7:25	YES	19:30	
			18NOV2011	YES	7:25	YES	19:35	
			19NOV2011	YES	7:30	YES	19:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	093	17	20NOV2011	YES	7:30	YES	19:35	
			21NOV2011	YES	7:30	YES	19:40	
			22NOV2011	YES	7:30	YES	19:40	
			23NOV2011	YES	7:30	YES	19:00	
			24NOV2011	YES	7:30	YES	19:10	
			25NOV2011	YES	7:30	YES	19:10	
			26NOV2011	YES	7:30	YES	19:15	
			27NOV2011	YES	7:31	YES	19:00	
			28NOV2011	YES	7:32	YES	19:15	
			29NOV2011	YES	7:32	YES	19:30	
			30NOV2011	YES	7:30	YES	19:30	
			01DEC2011	YES	7:40	YES	19:30	
			02DEC2011	YES	7:00	YES	19:00	
			03DEC2011	YES	7:00	YES	19:00	
			04DEC2011	YES	7:00	YES	19:00	
			05DEC2011	YES	7:00	YES	20:00	
			06DEC2011	YES	7:00			
	097	12	19NOV2010	YES		YES		
			20NOV2010	YES		YES		
			21NOV2010	YES		YES		
			22NOV2010	YES		YES		
			23NOV2010	YES		YES		
			24NOV2010	YES		YES		
			25NOV2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	097	12	26NOV2010	YES		YES		
			27NOV2010	YES		YES		
			28NOV2010	YES		YES		
			29NOV2010	YES		YES		
			30NOV2010	YES		YES		
			01DEC2010	YES		YES		
			01DEC2010	YES		YES		
			03DEC2010	YES		YES		
			04DEC2010	YES		YES		
			05DEC2010	YES		YES		
			06DEC2010	YES		YES		
			07DEC2010	YES		YES		
			08DEC2010	YES		YES		
			09DEC2010	YES		YES		
			10DEC2010	YES		YES		
			11DEC2010	YES		YES		
			12DEC2010	YES		YES		
			13DEC2010	YES		YES		
			14DEC2010			YES		
			15DEC2010	YES		YES		
			16DEC2010	YES		YES		
			17DEC2010	YES		YES		
			18DEC2010	YES		YES		
			19DEC2010	YES		YES		
			20DEC2010	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	097	12	21DEC2010	YES		YES		
			22DEC2010	YES		YES		
			23DEC2010	YES		YES		
			24DEC2010	YES		NO		
			25DEC2010	YES		YES		
			26DEC2010	YES		YES		
			27DEC2010	YES		YES		
			28DEC2010	YES		YES		
			29DEC2010	YES		YES		
			30DEC2010	YES		YES		
			01JAN2011	YES		YES		
			02JAN2011	YES		YES		
			03JAN2011	YES		YES		
			04JAN2011	YES		YES		
			05JAN2011	YES		YES		
			06JAN2011	YES		YES		
			07JAN2011	YES		YES		
			08JAN2011	YES		YES		
			09JAN2011	YES		YES		
			10JAN2011	YES		YES		
			11JAN2011	YES		YES		
			12JAN2011	YES		YES		
			13JAN2011	YES		YES		
			14JAN2011	YES		YES		
			15JAN2011	YES		YES		

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	097	12	16JAN2011	YES		YES		
			17JAN2011	YES		YES		
			18JAN2011	YES		YES		
			19JAN2011	YES		YES		
			20JAN2011	YES		YES		
			21JAN2011	YES		YES		
			22JAN2011	YES		YES		
			23JAN2011	YES		YES		
			24JAN2011	YES		YES		
			25JAN2011	YES		YES		
			26JAN2011	YES		YES		
			27JAN2011	YES		YES		
			28JAN2011	YES		YES		
			29JAN2011	YES		YES		
			30JAN2011	YES		YES		
			31JAN2011	YES		YES		
			01FEB2011	YES		YES		
			02FEB2011	YES		YES		
			03FEB2011	YES		YES		
			04FEB2011	YES		YES		
			05FEB2011	YES		YES		
			06FEB2011	YES		YES		
			07FEB2011	YES		YES		
			08FEB2011	YES		YES		
			09FEB2011	YES				

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
ACI-91	097	12	09FEB2011			YES		
			10FEB2011	YES		YES		
			11FEB2011	YES		YES		
			12FEB2011	YES		YES		
			13FEB2011	YES		YES		
			14FEB2011	YES		YES		
			15FEB2011	YES		YES		
			16FEB2011	NO		YES		Krankenhaus
Placebo	001	1	09APR2009	YES	13:00	YES	19:15	Beginn
			10APR2009	YES	8:15	YES	18:50	
			11APR2009	YES	8:15	YES	18:35	Schwindlig + schlecht
			12APR2009	YES	8:20	YES	18:25	Schwindlig + schlecht
			13APR2009	YES	8:15	YES	18:00	
			14APR2009	YES	8:30	YES	18:30	
			15APR2009	YES	8:30	YES	17:45	
			16APR2009	YES	8:30	YES	17:30	
			17APR2009	YES	8:30		17:30	
			18APR2009	YES	8:20	YES	18:30	
			19APR2009	YES	8:15	YES	18:00	
			20APR2009	YES	8:15	YES	17:30	
			21APR2009	YES	8:30	YES	18:00	
			22APR2009	YES	8:30	YES	18:00	
			23APR2009	YES	8:30	YES	18:00	
			24APR2009	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	25APR2009	YES	8:30	YES	18:30	
			26APR2009	YES	8:30	YES	18:00	
			27APR2009	YES	8:30	YES	18:00	
			28APR2009	YES	8:00	YES	18:00	
			29APR2009	YES	8:30	YES	18:00	
			30APR2009	YES	9:30		18:30	
			01MAY2009	YES	8:30	YES	18:00	
			02MAY2009	YES	8:30	YES	17:30	
			03MAY2009	YES	8:30	YES	18:00	
			04MAY2009	YES	8:30	YES	18:30	
			06MAY2009	YES	8:30	YES	18:00	
			07MAY2009	YES	8:00			
			07MAY2009	YES	8:00	NO	18:30	08:30 von den alten Tabletten
			08MAY2009	YES	8:30	YES	18:00	
			09MAY2009	YES	8:30	YES	18:00	
			10MAY2009	YES	8:30	YES	18:30	
			11MAY2009	YES	8:30	YES	18:00	
			12MAY2009	YES	8:30	YES	17:40	
			13MAY2009	YES	8:30	YES	18:00	
			14MAY2009	YES	8:30	YES	18:30	
			15MAY2009	YES	8:00	YES	18:00	
			16MAY2009	YES	8:45	YES	17:30	Vorm Bett gehen schlecht geworden. Kreislauf - vermutlich.
			17MAY2009	YES	8:30	YES	18:00	
			18MAY2009	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	19MAY2009		8:30	YES	17:30	
			20MAY2009	YES	8:30	YES	18:30	
			21MAY2009	YES	8:30	YES	18:00	
			22MAY2009	YES	8:30	YES	17:30	
			23MAY2009	YES	8:30	YES	18:30	
			24MAY2009	YES	8:30	YES	18:00	
			25MAY2009	YES	8:30	YES	17:30	
			26MAY2009	YES	8:30	YES	17:30	
			27MAY2009	YES	8:30	YES	17:30	
			28MAY2009	YES	8:30	YES	17:30	
			29MAY2009	YES	8:30	YES	17:30	
			30MAY2009	YES	8:30	YES	17:30	
			31MAY2009	YES	8:30	YES	17:30	
			01JUN2009	YES	8:30	YES	18:00	
			02JUN2009	YES	8:30	YES	17:30	
			03JUN2009	YES	8:30	YES	17:00	
			04JUN2009	YES	8:30	YES	17:00	
			05JUN2009	YES	8:00	YES	18:00	
			06JUN2009	YES	8:30	YES	17:30	
			07JUN2009	YES	8:30	YES	17:00	
			08JUN2009	YES	8:30	YES	17:30	
			09JUN2009	YES	9:00	YES	17:30	
			10JUN2009	YES	6:00	YES	17:00	
			11JUN2009	YES	8:30	YES	18:30	
			12JUN2009	YES	8:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	13JUN2009	YES	8:45	YES	18:00	
			14JUN2009	YES	8:30	YES	18:00	
			15JUN2009	YES	8:30	YES	17:45	
			16JUN2009	YES	8:30	YES	17:00	
			17JUN2009	YES	8:30	YES	17:30	
			18JUN2009	YES	8:30	YES	17:00	Ramipril 1/2 Tablette comp.
			19JUN2009	YES	8:45	YES	18:00	
			20JUN2009	YES	8:45	YES	17:30	
			21JUN2009	YES	8:30	YES	17:30	
			22JUN2009	YES	8:40	YES	18:30	
			23JUN2009	YES	8:40	YES	17:30	
			24JUN2009	YES	8:00	YES	18:30	
			25JUN2009	YES	8:30	YES	17:30	1 Tablette Ramipril comp.
			26JUN2009	YES	8:30	YES	18:00	
			27JUN2009	YES	8:30	YES	18:30	
			28JUN2009	YES	8:30	YES	17:30	
			29JUN2009	YES	8:40	YES	18:00	
			30JUN2009	YES	8:30	YES	17:30	
			01JUL2009	YES	8:00	YES	18:30	
			02JUL2009	YES	8:30	YES	18:00	
			03JUL2009	YES	8:30	YES	18:00	
			04JUL2009	YES	8:30	YES	17:30	
			05JUL2009	YES	8:30	YES	18:30	
			06JUL2009	YES	8:30	YES	18:00	
			07JUL2009			YES	18:00	3.

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	07JUL2009	YES	7:45			
			08JUL2009	YES	8:30	YES	17:30	
			09JUL2009	YES	8:30	YES	18:00	
			10JUL2009	YES	8:30	YES	18:00	
			11JUL2009	YES	8:30	YES	18:00	
			12JUL2009	YES	8:30	YES	18:00	
			13JUL2009	YES	8:30	YES	18:00	
			14JUL2009	YES	8:30	YES	17:45	
			15JUL2009	YES	8:30	YES	18:15	
			16JUL2009	YES	8:30	YES	18:00	
			17JUL2009	YES	8:45	YES	18:00	
			18JUL2009	YES	8:45	YES	17:30	
			19JUL2009	YES	8:30	YES	18:00	
			20JUL2009	YES	8:00	YES	18:10	
			21JUL2009	YES	8:45	YES	18:30	
			22JUL2009	YES	8:15	YES	18:00	
			23JUL2009	YES	8:30	YES	18:00	
			24JUL2009	YES	8:15		18:00	
			25JUL2009	YES	8:30	YES	18:15	Ganzen Tag nervöser Magen, bettlägrig
			26JUL2009	YES	8:15	YES	18:00	
			27JUL2009	YES	8:30	YES	18:30	
			28JUL2009	YES	8:30	YES	18:30	
			29JUL2009	YES	8:25	YES	18:30	
			30JUL2009	YES	8:15	YES	17:30	
			31JUL2009	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	01AUG2009	YES	8:15	YES	18:30	
			02AUG2009	YES	8:30	YES	18:30	
			03AUG2009	YES	8:15	YES	18:30	
			04AUG2009	YES	8:30	YES	18:00	
			05AUG2009	YES	8:15	YES	18:30	
			06AUG2009	YES	8:30	YES	18:30	
			07AUG2009	YES	8:30	YES	18:45	Nervöser Magen, den ganzen Tag zu Hause.
			08AUG2009	YES	8:30	YES	18:45	
			09AUG2009	YES	8:30	YES	18:45	
			10AUG2009	YES	8:30	YES	18:00	
			11AUG2009	YES	8:30	YES	18:15	
			12AUG2009	YES	8:15	YES	18:00	
			13AUG2009	YES	8:30	YES	18:00	
			14AUG2009	YES	8:30	YES	18:15	
			15AUG2009	YES	8:30	YES	18:15	
			16AUG2009	YES	8:30	YES	18:00	
			17AUG2009	YES	8:45	YES	18:30	
			18AUG2009	YES	8:30	YES	18:30	
			19AUG2009	YES	8:15	YES	18:00	Nervöser Magen sehr schlimm.
			20AUG2009	YES	8:15	YES	18:00	
			21AUG2009	YES	8:15	YES	18:30	
			22AUG2009	YES	8:30	YES	18:15	
			23AUG2009	YES	8:45	YES	18:30	
			24AUG2009	YES	8:00	YES	18:00	
			25AUG2009	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	26AUG2009	YES	8:45	YES	18:00	
			27AUG2009	YES	8:45	YES	18:40	
			28AUG2009	YES	8:30	YES	19:00	
			29AUG2009	YES	8:15		18:00	
			30AUG2009	YES	8:45	YES	18:30	Nervöser Magen ganzer Tag
			31AUG2009	YES	8:45	YES	18:30	
			01SEP2009	YES	8:30	YES	18:30	
			02SEP2009	YES	8:45	YES	18:30	
			03SEP2009	YES	8:20	YES	18:30	
			04SEP2009	YES	8:30	YES	18:30	
			05SEP2009	YES	8:30	YES	18:30	
			05SEP2009	YES	8:45	YES	18:15	
			06SEP2009	YES	8:30	YES	18:40	
			07SEP2009	YES	8:30	YES	18:00	
			08SEP2009	YES	8:30	YES	18:00	
			09SEP2009	YES	8:30	YES	18:45	
			10SEP2009	YES		YES	18:45	
			11SEP2009	YES	8:40	YES	18:30	
			12SEP2009	YES	8:30	YES	18:00	
			13SEP2009	YES	8:25	YES	18:15	
			14SEP2009	YES	8:30	YES	18:40	
			15SEP2009	YES	8:30	YES	18:30	
			16SEP2009	YES	8:10	YES	18:00	
			17SEP2009	YES	8:00			
			17SEP2009	YES	8:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	18SEP2009	YES	8:30	YES	19:00	
			19SEP2009	YES	8:00	YES	19:00	
			20SEP2009	YES	8:30	YES	18:00	
			21SEP2009	YES	8:00	YES	18:30	
			22SEP2009	YES	8:15	YES	18:30	
			23SEP2009	YES	8:15	YES	19:00	
			24SEP2009	YES	8:15	YES	18:45	
			25SEP2009	YES	8:15	YES	18:00	
			26SEP2009	YES	8:15	YES	18:00	
			27SEP2009	YES	8:15	YES	18:00	
			28SEP2009	YES	8:30	YES	18:00	
			29SEP2009	YES	8:30	YES	18:30	
			30SEP2009	YES	8:30	YES	18:00	
			01OCT2009	YES	8:15	YES	19:00	
			02OCT2009	YES	8:30	YES	18:30	
			03OCT2009	YES	8:15	YES	18:30	
			04OCT2009	YES	8:30	YES	18:30	
			05OCT2009	YES	8:15	YES	18:00	
			06OCT2009	YES	8:15	YES	18:45	
			07OCT2009	YES	8:30	YES	18:35	
			08OCT2009	YES	8:15	YES	18:15	
			09OCT2009	YES	8:30	YES	18:30	
			10OCT2009	YES	8:30	YES	18:45	128/70/65 innerliches Zittern ganz komisch im Kopf
			11OCT2009	YES	8:30	YES	19:00	
			12OCT2009	YES	8:20	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	13OCT2009	YES	8:15	YES	18:00	
			14OCT2009	YES	8:30	YES	18:30	
			15OCT2009	YES	8:20	YES	18:40	
			16OCT2009	YES	8:30	YES	18:00	
			17OCT2009	YES	8:30	YES	18:30	
			18OCT2009	YES	9:45	YES	18:30	
			19OCT2009	YES	9:45	YES	18:30	
			20OCT2009	YES	8:30	YES	18:30	
			21OCT2009	YES	8:30	YES	18:30	
			22OCT2009	YES	8:30	YES	18:45	
			23OCT2009	YES	8:40	YES	18:50	
			24OCT2009	YES	8:30	YES	18:40	
			25OCT2009	YES	8:30	YES	18:30	
			26OCT2009	YES	8:25	YES	18:30	
			26OCT2009	YES	8:45	YES	19:00	
			27OCT2009	YES	8:30	YES	18:30	
			28OCT2009	YES	8:25	YES	18:30	
			29OCT2009	YES	8:30	YES	18:45	Zittriger Magen, schwach
			30OCT2009	YES	8:45	YES	18:15	Zittriger Magen, schwach
			31OCT2009	YES	8:15	YES	18:30	
			01NOV2009	YES	8:30	YES	18:30	
			02NOV2009	YES	8:15	YES	18:45	
			03NOV2009	YES	8:40	YES	18:15	Zittern im Magen
			04NOV2009	YES	8:30	YES	18:30	Schwindlig + zittern im Magen
			05NOV2009	YES	8:10	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	06NOV2009	YES	8:15	YES	19:00	
			07NOV2009	YES	8:30	YES	19:00	
			08NOV2009	YES	8:45	YES	19:00	Schwach + zittriger Magen
			09NOV2009	YES	8:45	YES	18:30	
			10NOV2009	YES	9:00	YES	18:45	
			11NOV2009	YES	8:45	YES	18:45	
			12NOV2009	YES	8:30	YES	19:00	Schwach + zittriger Magen
			13NOV2009	YES	8:30	YES	18:30	
			14NOV2009	YES	8:30	YES	18:45	
			15NOV2009	YES	9:00	YES	19:00	Kopfrauschen, schwindelig, zittern Magen
			16NOV2009	YES	8:30	YES	18:35	
			17NOV2009	YES	8:30	YES	18:45	
			18NOV2009	YES	8:30	YES	18:30	
			19NOV2009	YES	8:30	YES	19:00	
			20NOV2009	YES	8:30	YES	18:45	
			21NOV2009	YES	8:30	YES	19:00	
			22NOV2009	YES	8:30	YES	18:35	
			23NOV2009	YES	8:30	YES	18:30	
			24NOV2009	YES	8:30	YES	19:00	Schwach, zittriger Magen
			25NOV2009	YES	8:45	YES	18:45	
			26NOV2009	YES	8:30	YES	18:40	
			27NOV2009	YES	8:45	YES	18:30	
			28NOV2009	YES	8:30	YES	18:45	
			29NOV2009	YES	8:30	YES	19:00	
			30NOV2009	YES	8:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	01DEC2009	YES	8:30	YES	19:00	Zittrig + schwach, Schwindel
			02DEC2009	YES	8:30	YES	18:45	
			03DEC2009	YES	8:00	YES	19:00	
			04DEC2009	YES	8:30	YES	18:45	
			05DEC2009	YES	8:30	YES	19:00	
			06DEC2009	YES	8:30	YES	18:30	Magenzittern, schwach + schwindelig
			07DEC2009	YES	8:30	YES	19:00	
			08DEC2009	YES	8:30	YES	18:55	
			09DEC2009	YES	8:45	YES	18:30	
			10DEC2009	YES	7:30			
			10DEC2009	YES		YES	18:30	Einnahme morgens, Uhrzeit: Klinik
			11DEC2009	YES	8:30	YES	18:45	
			12DEC2009	YES	8:30	YES	18:40	
			13DEC2009	YES	8:30	YES	18:30	
			14DEC2009	YES	8:30	YES	18:45	
			15DEC2009	YES	8:30	YES	18:20	
			16DEC2009	YES	8:30	YES	19:00	
			17DEC2009	YES	8:35	YES	18:40	
			18DEC2009	YES	8:30	YES	19:20	
			19DEC2009	YES	8:30	YES	19:00	
			20DEC2009	YES	8:30	YES	18:45	
			21DEC2009	YES	8:30	YES	19:10	
			22DEC2009	YES	8:45	YES	18:30	
			23DEC2009	YES	8:30	YES	19:00	
			24DEC2009	YES	8:30	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	25DEC2009	YES		YES	18:30	
			27DEC2009	YES	8:45	YES	18:50	
			28DEC2009	YES	8:45	YES	18:30	
			29DEC2009	YES	8:30	YES	18:20	
			30DEC2009	YES	8:35	YES	18:25	
			31DEC2009	YES	8:30	YES	20:00	
			01JAN2010	YES	9:00	YES	18:20	
			02JAN2010	YES	9:00	YES	18:30	
			03JAN2010	YES	9:00	YES	18:30	
			04JAN2010	YES	8:30	YES	18:15	
			05JAN2010	YES	8:30	YES	18:30	Cipro Basics 250 mg Beginn 1 x tgl. wg. Harnwegsinfekt lt. Ehemann. Telefonat mit Hausarzt Dr. Heublij am 28.04.2010: ab 05.01. Bisoprolol 2,5 mg ½ - 0 - ½ wg. rez. "Magenzittern", essentl. Tremor
			06JAN2010	YES	8:30	YES	18:30	
			07JAN2010	YES	8:15	YES	18:45	
			08JAN2010	YES	8:55	YES	18:30	
			09JAN2010	YES	9:00	YES	18:30	
			10JAN2010	YES	8:45	YES	18:30	
			11JAN2010	YES	9:00	YES	18:30	
			12JAN2010	YES	8:30	YES	18:30	
			13JAN2010	YES	8:50	YES	18:30	
			14JAN2010	YES	9:00	YES	18:30	
			15JAN2010	YES	8:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	16JAN2010	YES	8:30	YES	19:00	
			17JAN2010	YES	8:30	YES	18:30	
			18JAN2010	YES	8:30	YES	18:35	
			19JAN2010	YES	8:30	YES	18:30	Schwindelitz 108-55-98,09:30
			20JAN2010	YES	8:15	YES	18:55	
			21JAN2010	YES	8:30	YES	18:30	
			22JAN2010	YES	8:45	YES	18:30	
			23JAN2010	YES	8:35	YES	18:30	
			24JAN2010	YES	8:40	YES	18:30	
			25JAN2010	YES	8:30	YES	18:40	
			26JAN2010	YES	8:30	YES	18:30	
			27JAN2010	YES	8:00	YES	18:00	
			28JAN2010	YES	8:30	YES	18:15	
			29JAN2010	YES	8:45	YES	18:20	
			30JAN2010	YES	8:45	YES	18:30	
			31JAN2010	YES	8:30	YES	18:30	
			01FEB2010	YES	8:30	YES	18:30	
			02FEB2010	YES	8:30	YES	18:45	
			03FEB2010	YES	8:30	YES	18:30	
			04FEB2010	YES	8:50	YES	18:30	
			05FEB2010	YES	9:00	YES	18:30	Harnwegsentzündung Cipro-Basics abgesetzt lt. Ehemann, Telefonat mit Hausarzt Dr. Heulbij am 28.04.2010: Ab 05.02. w. Harnwegsinfekt Ciprofloxacin 250 mg 1-0-1 für 5 Tage
			06FEB2010	YES	8:35	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	07FEB2010	YES	8:30	YES	18:30	
			08FEB2010	YES	8:30	YES	18:45	
			09FEB2010	YES	8:00	YES	18:00	
			10FEB2010	YES	8:30	YES	18:30	
			11FEB2010	YES	8:30	YES	18:30	
			12FEB2010	YES	8:45	YES	18:30	
			13FEB2010	YES	8:30	YES	18:30	
			14FEB2010	YES	8:45	YES	18:30	
			15FEB2010	YES	8:30	YES	18:30	
			16FEB2010	YES	8:35	YES	18:30	
			17FEB2010	YES	8:30	YES	18:30	
			18FEB2010	YES	8:30	YES	18:20	
			19FEB2010	YES	8:30	YES	18:30	
			20FEB2010	YES	8:30	YES	18:30	
			21FEB2010	YES	8:45	YES	18:30	
			22FEB2010	YES	9:00	YES	18:30	
			23FEB2010	YES	8:40	YES	18:30	
			24FEB2010	YES	8:30	YES	18:30	
			25FEB2010	YES	8:15	YES	18:00	
			26FEB2010	YES	8:30	YES	18:30	
			27FEB2010	YES	8:30	YES	18:45	
			28FEB2010	YES	8:30	YES	18:00	
			01MAR2010	YES	8:30	YES	18:30	
			02MAR2010	YES	8:30	YES	18:30	
			03MAR2010	YES	8:35	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	04MAR2010	YES	8:30	YES	18:40	
			05MAR2010	YES	8:30	YES	18:30	
			06MAR2010	YES	8:30	YES	18:40	
			07MAR2010	YES	8:30	YES	19:00	
			08MAR2010	YES	8:30	YES	18:45	
			09MAR2010	YES	8:30	YES	18:30	
			10MAR2010	YES	8:30	YES	18:20	
			11MAR2010	YES	8:30	YES	18:30	
			12MAR2010	YES	8:30	YES	18:30	
			13MAR2010	YES	8:30	YES	18:30	
			14MAR2010	YES	8:30	YES	18:45	
			15MAR2010	YES	8:30	YES	18:30	
			16MAR2010	YES	8:30	YES	18:20	
			17MAR2010	YES	8:25	YES	18:30	
			18MAR2010	YES	8:30	YES	18:30	
			19MAR2010	YES	8:30	YES	18:00	
			20MAR2010	YES	8:30	YES	18:30	
			21MAR2010	YES	8:30	YES	18:30	
			22MAR2010	YES	8:30	YES	18:30	
			23MAR2010	YES	8:30	YES	18:40	
			24MAR2010	YES	8:30	YES	18:30	
			25MAR2010	YES	8:50	YES	18:30	
			26MAR2010	YES	8:00	YES	18:00	
			27MAR2010	YES	8:30	YES	18:30	
			28MAR2010	YES	8:40	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	001	1	29MAR2010	YES	8:30	YES	18:20	
			30MAR2010	YES	8:30	YES	18:40	
			31MAR2010	YES	8:40	YES	18:30	
			01APR2010	YES	8:30	YES	18:50	
			02APR2010	YES	8:30	YES	18:15	
			03APR2010	YES	8:30	YES	19:00	
			04APR2010	YES	8:30	YES	18:30	
			05APR2010	YES	8:45	YES	18:30	
			06APR2010	YES	8:35	YES	18:30	
			07APR2010	YES	7:30	YES	18:00	
			08APR2010	YES	7:50			
	003	1	28MAY2009	YES	12:00	YES	17:59	
			29MAY2009	YES	6:11	YES	18:15	
			30MAY2009	YES	5:02	YES	17:29	
			31MAY2009	YES	7:52	YES	17:42	
			01JUN2009	YES	7:06	YES	21:34	
			02JUN2009	YES	7:52	YES	17:49	
			03JUN2009	YES	6:14	YES	21:43	Geschäftssessen bis 20:38 h. Wartezeit bis 21:43. Nachtisch um 22:19 h (36').
			04JUN2009	YES	5:28	YES	21:39	Vorher Essenseinladung bis 19:51 - Pause (total) bis 21:39.
			05JUN2009	YES	6:34	YES	17:51	
			06JUN2009	YES	8:18	YES	17:21	Citalopram (5 mg) um 08:39 eingenommen.
			07JUN2009	YES	6:30	YES	19:48	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	08JUN2009	YES	6:46	YES	18:37	
			09JUN2009	YES	6:16	YES	17:18	
			10JUN2009	YES	6:00	YES	17:17	
			11JUN2009	YES	7:16	YES	17:35	
			12JUN2009	YES	7:21	YES	17:49	
			13JUN2009	YES	7:26	YES	17:34	
			14JUN2009	YES	5:52	YES	18:21	
			15JUN2009	YES	6:32	YES	16:40	
			16JUN2009	YES	6:22	YES	16:46	
			17JUN2009	YES	6:11	YES	16:49	
			18JUN2009	YES	6:38	YES	17:45	
			19JUN2009	YES	7:59	YES	17:14	
			20JUN2009	YES	7:13	YES	18:30	
			21JUN2009	YES	7:48	YES	17:19	
			22JUN2009	YES	6:22	YES	16:59	
			23JUN2009	YES	7:07	YES	18:54	Nach 28' 1 Glas Milch
			24JUN2009	YES	6:04			
			24JUN2009	YES	6:12	YES	18:24	Morgens Tablette (06:12 h), innerhalb der Zeit vor der 2. Visite, heute um 09 h.
			25JUN2009	YES	6:01	YES	18:53	
			26JUN2009	YES	6:27	YES	17:48	
			27JUN2009	YES	7:17	YES	19:39	
			28JUN2009	YES	6:35	YES	18:36	
			29JUN2009	YES	6:03	YES	18:16	
			30JUN2009	YES	6:44	YES	18:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	01JUL2009	YES	5:46	YES	17:27	
			02JUL2009	YES	6:05	YES	17:17	
			03JUL2009	YES	7:01	NO		s. Extrablatt! Heute Einnahmebeginn Exelon 3,0 mg Kapseln! Statt 9,5 mg. Pflaster Dosis: 4x3 mg = 12 mg/tgl.
			04JUL2009	YES	7:54	YES	19:09	
			05JUL2009	YES	7:00	YES	19:07	
			06JUL2009	YES	6:03	YES	18:12	
			07JUL2009	YES	6:00	YES	16:57	
			08JUL2009	YES	5:53	YES	18:41	
			09JUL2009	YES	6:02	YES	18:17	
			10JUL2009	YES	4:21	YES	17:25	
			11JUL2009	YES	6:07	YES	17:03	
			12JUL2009	YES	7:07	YES	17:53	
			13JUL2009	YES	6:16	YES	17:33	
			14JUL2009	YES	5:15	YES	17:56	
			15JUL2009	YES	6:20	YES	16:22	
			16JUL2009	YES	5:35	YES	17:57	
			17JUL2009	YES	6:27	YES	18:33	
			18JUL2009	YES	7:00	YES	21:31	
			19JUL2009	YES	5:46	YES	18:08	
			20JUL2009	YES	6:26	YES	18:15	
			21JUL2009	YES	5:30	YES	18:54	
			22JUL2009	YES	5:32	YES	18:52	
			23JUL2009	YES	5:29	YES	17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	24JUL2009	YES	6:42	YES	17:27	
			25JUL2009	YES	6:30	YES	20:25	
			26JUL2009	YES	7:01	YES	19:21	
			27JUL2009	YES	6:20	YES	17:17	
			28JUL2009	YES	5:58	YES	17:15	
			29JUL2009	YES	6:16	YES	18:41	
			30JUL2009	YES	5:58	YES	19:34	
			31JUL2009	YES	6:10	YES	17:33	
			01AUG2009	YES	6:46	YES	18:58	
			02AUG2009	YES	7:47	YES	19:21	
			03AUG2009	YES	6:09	YES	17:14	
			04AUG2009	YES	6:18	YES	17:55	
			05AUG2009	YES	6:24	YES	21:04	
			06AUG2009	YES	6:02	YES	20:57	
			07AUG2009	YES	6:09	YES	18:42	
			08AUG2009	YES	6:08	YES	20:15	
			09AUG2009	YES	6:06	YES	20:34	
			10AUG2009	YES	6:15	YES	17:16	
			11AUG2009	YES	6:12	YES	17:59	
			12AUG2009	YES	7:05	YES	17:35	
			13AUG2009	YES	6:52	YES	19:40	
			14AUG2009	YES	7:36	YES	17:27	
			15AUG2009	YES	6:41	YES	17:06	
			16AUG2009	YES	7:09	YES	21:45	Abendessen bis 20:10 h.
			17AUG2009	YES	5:53	YES	19:17	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	18AUG2009	YES	7:08	YES	21:45	
			19AUG2009	YES	7:16	YES	19:37	
			20AUG2009	YES	7:22	YES	17:18	
			21AUG2009	YES	6:41	YES	17:20	
			22AUG2009	YES	7:11	YES	16:30	
			23AUG2009	YES	7:08	YES	18:05	
			24AUG2009	YES	5:59	YES	19:39	
			25AUG2009	YES	6:00			
			25AUG2009			YES	18:02	Neustart Visit No. 3 25.08.2009/11:00 h
			26AUG2009	YES	5:55	YES	17:04	
			27AUG2009	YES	5:59	YES	18:12	
			28AUG2009	YES	6:03	YES	17:37	
			29AUG2009	YES	5:51	YES	17:40	
			30AUG2009	YES	7:07	YES	20:07	
			31AUG2009	YES	5:52	YES	17:04	
			01SEP2009	YES	6:11	YES	17:02	
			02SEP2009	YES	5:46	YES	18:02	
			03SEP2009	YES	5:20	YES	17:47	
			04SEP2009	YES	6:38	YES	16:40	
			05SEP2009	YES	6:47	YES	17:30	
			06SEP2009	YES	7:29	YES	17:34	
			07SEP2009	YES	6:31	YES	16:59	
			08SEP2009	YES	5:42	YES	18:28	
			09SEP2009	YES	5:41	YES	17:27	
			10SEP2009	YES	5:28	YES	17:17	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	11SEP2009	YES	5:33	YES	17:26	
			12SEP2009	YES	7:35	YES	17:20	
			13SEP2009	YES	7:31	YES	17:55	
			14SEP2009	YES	5:35	YES	17:08	
			15SEP2009	YES	5:28	YES	17:52	
			16SEP2009	YES	6:39	YES	17:18	
			17SEP2009	YES	6:01	YES	17:14	
			18SEP2009	YES	6:02	YES	17:32	
			19SEP2009	YES	7:13	YES	17:35	
			20SEP2009	YES	6:21	YES	19:58	
			21SEP2009	YES	7:27	YES	22:31	ca. 2 Std. n. Ende einer Veranstaltg.
			22SEP2009	YES	5:48	YES	17:53	
			23SEP2009	YES	6:03	YES	17:26	
			24SEP2009	YES	4:56	YES	16:20	
			25SEP2009	YES	5:31	YES	17:21	
			26SEP2009	YES	6:50	YES	17:15	
			27SEP2009	YES	7:31	YES	19:14	
			28SEP2009	YES	5:35	YES	18:04	
			29SEP2009	YES	5:33	YES	17:18	
			30SEP2009	YES	6:10	YES	17:07	
			01OCT2009	YES	5:54	YES	17:46	
			02OCT2009	YES	5:53	YES	17:50	
			03OCT2009	YES	7:19	YES	18:51	
			04OCT2009	YES	7:32	YES	19:09	
			05OCT2009	YES	5:50	YES	17:17	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	06OCT2009	YES	5:29	YES	17:34	
			07OCT2009	YES	6:03	YES	17:31	
			08OCT2009	YES	5:37	YES	17:33	
			09OCT2009	YES	5:58	YES	16:54	
			10OCT2009	YES	4:31	YES	19:31	
			11OCT2009	YES	7:25	YES	18:57	
			12OCT2009	YES	6:04	YES	18:02	
			13OCT2009	YES	6:02	YES	17:29	
			14OCT2009	YES	5:28	YES	17:37	
			15OCT2009	YES	5:27	YES	17:00	
			16OCT2009	YES	7:41	YES	19:38	
			17OCT2009	YES	7:18	YES	19:26	
			18OCT2009	YES	7:40	YES	21:24	
			19OCT2009	YES	5:59	YES	17:24	
			20OCT2009	YES	5:59	YES	18:05	
			21OCT2009	YES	6:07	YES	17:29	
			22OCT2009	YES	5:40	YES	18:13	
			22OCT2009	YES	7:09	YES	18:02	
			23OCT2009	YES	6:07	YES	17:19	
			24OCT2009	YES	8:20	YES	17:50	
			25OCT2009	YES	7:26	YES	18:25	
			26OCT2009	YES	5:34	YES	17:25	
			27OCT2009	YES	6:06	YES	17:31	
			28OCT2009	YES	6:00	YES	17:10	
			29OCT2009	YES	5:53	YES	17:45	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	30OCT2009	YES	6:32	YES	17:29	
			31OCT2009	YES	5:32	YES	22:07	
			01NOV2009	YES	7:29	YES	19:29	("!")
			02NOV2009	YES	6:30	YES	17:46	
			03NOV2009	YES	6:01	YES	16:39	
			04NOV2009	YES	5:24	YES	17:27	
			05NOV2009	YES	5:30	YES	17:31	
			06NOV2009	YES	6:41	YES	17:37	
			07NOV2009	YES	8:23	YES	17:03	
			08NOV2009	YES	8:14	YES	17:40	
			09NOV2009	YES	6:10	YES	19:13	
			10NOV2009	YES	6:42	YES	17:33	
			11NOV2009	YES	5:42	YES	17:43	
			12NOV2009	YES	6:01			
			12NOV2009			YES	17:50	Beginn 12.11.2009, 17:50 h. Vormittags: noch 1 Tablette des alten Visit (Visit 3)
			13NOV2009	YES	6:54	YES	19:47	
			14NOV2009	YES	9:50	YES	21:49	
			15NOV2009	YES	7:53	YES	20:26	
			16NOV2009	YES	7:51	YES	17:25	
			17NOV2009	YES	6:41	YES	16:23	
			18NOV2009	YES	6:41	YES	17:04	
			19NOV2009	YES	6:41	YES	17:45	
			20NOV2009	YES	6:37	YES	17:47	
			21NOV2009	YES	8:21	YES	18:04	

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	23NOV2009	YES	6:44	YES	17:28	
			24NOV2009	YES	6:09	YES	17:42	
			25NOV2009	YES	6:37	YES	17:50	
			26NOV2009	YES	6:42	YES	17:49	
			27NOV2009	YES	7:09	YES	17:35	
			28NOV2009	YES	7:50	YES	17:08	
			29NOV2009	YES	8:18	YES	17:54	
			30NOV2009	YES	6:34	YES	17:39	
			01DEC2009	YES	7:01	YES	17:41	
			02DEC2009	YES	6:43	YES	17:54	
			03DEC2009	YES	6:23	YES	17:41	
			04DEC2009	YES	8:45	YES	17:04	
			05DEC2009	YES	7:12	YES	18:32	
			06DEC2009	YES	8:40	YES	17:57	
			07DEC2009	YES	6:23	YES	17:42	
			08DEC2009	YES	5:57	YES	17:42	
			09DEC2009	YES	6:20	YES	16:57	
			10DEC2009	YES	6:08	YES	17:40	
			11DEC2009	YES	5:35	YES	19:15	
			12DEC2009	YES	9:15	YES	17:18	
			13DEC2009	YES	10:13	YES	17:54	
			14DEC2009	YES	6:14	YES	17:17	
			15DEC2009	YES	6:02	YES	17:49	
			16DEC2009	YES	6:03	YES	17:39	
			17DEC2009	YES	6:03	YES	17:46	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	18DEC2009	YES	6:02	YES	17:47	
			19DEC2009	YES	6:58	YES	20:08	
			20DEC2009	YES	9:06	YES	18:40	
			21DEC2009	YES	5:46	YES	17:35	
			22DEC2009	YES	6:08	YES	17:34	
			23DEC2009	YES	5:49	YES	17:28	
			24DEC2009	YES	8:12	YES	17:35	
			25DEC2009	YES	7:22	YES	17:22	
			26DEC2009	YES	5:08	YES	19:32	
			27DEC2009	YES	6:55	YES	16:29	
			28DEC2009	YES	5:53	YES	18:08	
			29DEC2009	YES	6:27	YES	16:21	
			30DEC2009	YES	6:16	YES	17:00	
			31DEC2009	YES	8:05	YES	17:41	
			01JAN2010	YES	8:17	YES	17:40	
			02JAN2010	YES	7:19	YES	18:31	
			03JAN2010	YES	6:28	YES	17:01	
			04JAN2010	YES	6:15	YES	17:48	
			05JAN2010	YES	7:07	YES	16:47	
			06JAN2010	YES	8:26	YES	17:26	
			07JAN2010	YES	6:18	YES	17:26	
			08JAN2010	YES	6:15	YES	16:32	
			09JAN2010	YES	3:56	YES	16:42	
			10JAN2010	YES	8:15	YES	18:26	
			11JAN2010	YES	6:13	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	003	1	12JAN2010	YES	6:15	YES	17:30	
			13JAN2010	YES	6:15	YES	16:28	
			14JAN2010	YES	6:35	YES	18:02	
			15JAN2010	YES	7:14	YES	17:23	
			16JAN2010	YES	6:54	YES	19:18	
			17JAN2010	YES	7:40	YES	19:29	
			18JAN2010	YES	6:16	YES	17:32	
			19JAN2010	YES	6:03	YES	16:54	
			20JAN2010	YES	6:23	YES	16:44	
			21JAN2010	YES	6:02	YES	17:36	
			22JAN2010	YES	6:02	YES	17:27	
			23JAN2010	YES	7:17	YES	17:32	
			24JAN2010	YES	9:06	YES	17:26	
			25JAN2010	YES	6:03	YES	17:24	
			26JAN2010	YES	6:03	YES	17:32	
			27JAN2010	YES	1:49	YES	16:05	
			28JAN2010	YES	5:47	YES	17:44	
			29JAN2010	YES	5:23	YES	17:38	
			30JAN2010	YES	7:26	YES	18:45	
			31JAN2010	YES	8:28	YES	17:22	
			01FEB2010	YES	6:34	YES	17:07	
			02FEB2010	YES	7:01	YES	17:23	
			03FEB2010	YES	6:03	YES	17:19	
			04FEB2010	YES	6:04			

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2		YES	8:10	YES	20:00	
			04JUN2009			YES	18:30	
			05JUN2009	YES	8:10	YES	20:15	
			06JUN2009	YES	7:30	YES	20:15	
			07JUN2009	YES	8:15	YES	20:00	
			08JUN2009	YES	8:00	YES	20:45	
			09JUN2009	YES	7:45	YES	20:00	
			10JUN2009	YES	7:30	YES	20:15	
			11JUN2009	YES	8:15	YES	20:30	
			12JUN2009	YES	8:30	YES	20:00	
			13JUN2009	YES	8:00	YES	19:45	
			14JUN2009	YES	8:30	YES	18:30	
			14JUN2009	YES	7:45	YES	19:30	
			15JUN2009	YES	7:30	YES	19:30	
			15JUN2009	YES	7:30	YES	19:30	
			16JUN2009	YES	7:30	YES	20:00	
			17JUN2009	YES	7:45	YES	18:45	
			18JUN2009	YES	7:50	YES	18:45	
			19JUN2009	YES	7:45	YES	20:15	
			20JUN2009	YES	8:15	YES	18:45	
			21JUN2009	YES	7:45	YES	19:20	
			22JUN2009	YES	7:50	YES	19:00	
			23JUN2009	YES	7:50	YES	20:00	
			24JUN2009	YES	7:45	YES	19:00	
			25JUN2009	YES	7:30	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	26JUN2009	YES	7:30	YES	20:30	
			27JUN2009	YES	8:00	YES	19:00	
			28JUN2009	YES	7:45	YES	19:45	
			29JUN2009	YES	8:15	YES	19:45	
			30JUN2009	YES	7:15			
			30JUN2009	YES	7:15	YES	17:45	
			01JUL2009	YES	8:00	YES	19:00	
			02JUL2009	YES	7:20	YES	20:15	
			03JUL2009	YES	7:20	YES	19:30	
			04JUL2009	YES	7:30	YES	20:00	
			05JUL2009	YES	7:05	YES	19:15	
			06JUL2009	YES	8:00	YES	19:15	
			07JUL2009	YES	6:45	YES	20:10	
			08JUL2009	YES	6:50	YES	19:45	
			09JUL2009	YES	7:20	YES	19:40	
			10JUL2009	YES	7:20	YES	19:30	
			11JUL2009	YES	7:25	YES	19:45	
			12JUL2009	YES	7:30	YES	20:00	
			13JUL2009	YES	8:10	YES	19:00	
			14JUL2009	YES	7:15	YES	19:30	
			15JUL2009	YES	7:45	YES	19:50	
			16JUL2009	YES	7:15	YES	19:00	
			17JUL2009	YES	7:25	YES	20:30	
			18JUL2009	YES	6:45	YES	19:45	
			19JUL2009	YES	8:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	20JUL2009	YES	7:25	YES	19:00	
			21JUL2009	YES	7:00	YES	19:00	
			22JUL2009	YES	7:25	YES	19:00	
			23JUL2009	YES	7:30	YES	19:00	
			24JUL2009	YES	7:30	YES	19:00	
			25JUL2009	YES	7:00	YES	19:00	
			26JUL2009	YES	7:00	YES	20:00	
			27JUL2009	YES	7:20	YES	20:00	
			28JUL2009	YES	7:30	YES	20:00	
			29JUL2009	YES	5:25	YES	21:00	
			30JUL2009	YES	7:55	YES	21:00	
			31JUL2009	YES	7:00	YES	20:00	
			01AUG2009	YES	6:45	YES	20:00	
			02AUG2009	YES	7:25	YES	20:00	
			03AUG2009	YES	7:45	YES	20:00	
			04AUG2009	YES	7:00	YES	20:10	
			05AUG2009	YES	7:20	YES	20:15	
			06AUG2009	YES	6:50	YES	20:15	
			07AUG2009	YES	7:40	YES	20:00	
			08AUG2009	YES	10:15	YES	20:15	
			09AUG2009	YES	6:55	YES	20:00	
			10AUG2009	YES	7:15	YES	18:30	
			11AUG2009	YES	7:30	YES	20:00	
			12AUG2009	YES	7:15	YES	20:00	
			13AUG2009	YES	7:25	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	14AUG2009	YES	7:20	YES	20:00	
			15AUG2009	YES	7:15	YES	20:00	
			16AUG2009	YES	7:30	YES	20:00	
			17AUG2009	YES	7:30	YES	20:00	
			18AUG2009	YES	7:30	YES	20:00	
			19AUG2009	YES	7:40	YES	20:00	
			20AUG2009	YES	7:40	YES	20:00	
			21AUG2009	YES	7:45	YES	20:00	
			22AUG2009	YES	7:05	YES	19:45	
			23AUG2009	YES	7:00	YES	19:30	
			24AUG2009	YES	7:20	YES	19:30	
			25AUG2009	YES	7:20			
			25AUG2009	YES	7:20	YES	19:00	
			26AUG2009	YES	7:00	YES	20:00	
			27AUG2009	YES	7:00	YES	19:30	
			28AUG2009	YES	7:00	YES	19:00	
			29AUG2009	YES	7:00	YES	20:15	
			30AUG2009	YES	7:00	YES	20:00	
			31AUG2009	YES	7:00	YES	19:00	
			01SEP2009	YES	7:00	YES	19:00	
			02SEP2009	YES	7:30	YES	19:00	
			03SEP2009	YES	8:00	YES	19:00	
			04SEP2009	YES	7:40	YES	20:00	
			05SEP2009	YES	7:00	YES	20:00	
			06SEP2009	YES	7:00	YES	19:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	07SEP2009	YES	7:45	YES	19:45	
			08SEP2009	YES	7:20	YES	19:45	
			09SEP2009	YES	7:20	YES	19:55	
			10SEP2009	YES	7:30	YES	18:30	
			11SEP2009	YES	7:30	YES	19:45	
			12SEP2009	YES	7:35	YES	19:45	
			13SEP2009	YES	7:35	YES	19:45	
			14SEP2009	YES	7:45	YES	19:45	
			15SEP2009	YES	7:45	YES	19:45	
			16SEP2009	YES	7:45	YES	20:00	
			17SEP2009	YES	7:50	YES	20:00	
			18SEP2009	YES	7:30	YES	20:00	
			19SEP2009	YES	7:35	YES	20:00	
			20SEP2009	YES	7:50	YES	20:15	
			21SEP2009	YES	7:55	YES	20:00	
			22SEP2009	YES	7:45	YES	20:30	
			23SEP2009	YES	6:15	YES	16:45	
			24SEP2009	YES	7:30	YES	16:00	
			25SEP2009	YES	8:20	YES	17:30	
			26SEP2009	YES	8:00	YES	16:45	
			27SEP2009	YES	7:45	YES	18:00	
			28SEP2009	YES	8:00	YES	17:35	
			29SEP2009	YES	7:50	YES	17:30	
			30SEP2009	YES	8:35	YES	17:40	
			01OCT2009	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	02OCT2009	YES	8:00	NO		Abends vergessen einzunehmen
			03OCT2009	YES	9:45	YES	18:00	
			04OCT2009	YES	8:00	YES	17:45	
			05OCT2009	YES	7:45	YES	17:30	
			06OCT2009	YES	8:00	YES	18:00	
			07OCT2009	YES	7:30	YES	18:30	
			08OCT2009	YES	7:10	YES	18:30	
			09OCT2009	YES	7:45	YES	17:30	
			10OCT2009	YES	7:50	YES	18:15	
			11OCT2009	YES	8:05	YES	18:00	
			12OCT2009	YES	8:20	YES	18:00	
			13OCT2009	YES	8:20	YES	18:00	
			14OCT2009	YES	7:45	YES	18:45	
			15OCT2009	YES	7:45	YES	18:15	
			16OCT2009	YES	7:25	YES	17:45	
			17OCT2009	YES	8:00	YES	19:00	
			18OCT2009	YES	7:00	YES	19:00	
			19OCT2009	YES	7:30	YES	19:00	
			20OCT2009	YES	8:00	YES	20:00	
			21OCT2009	YES	8:00	YES	19:00	
			22OCT2009	YES	7:30	YES	19:00	
			23OCT2009	YES	8:30	YES	21:00	
			24OCT2009	YES	8:00	YES	20:00	
			25OCT2009	YES	7:45	YES	19:00	
			26OCT2009	YES	7:00	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	27OCT2009	YES	7:15	YES	20:00	
			28OCT2009	YES	7:30	YES	19:00	
			29OCT2009	YES	7:15	YES	20:15	
			30OCT2009	YES	7:20	YES	19:30	
			31OCT2009	YES	7:20	YES	19:30	
			01NOV2009	YES	8:00	YES	19:00	
			02NOV2009	YES	8:00	YES	19:00	
			03NOV2009	YES	7:15	YES	19:45	
			04NOV2009	YES	7:00	YES	19:45	
			05NOV2009	YES	7:45	YES	19:45	
			06NOV2009	YES	7:40	YES	19:50	
			07NOV2009	YES	7:45	YES	18:30	
			08NOV2009	YES	7:30	YES	18:40	
			09NOV2009	YES	8:00	YES	18:40	
			10NOV2009	YES	7:15	YES	18:15	
			11NOV2009	YES	7:00	YES	18:30	
			12NOV2009	YES	7:40	YES	19:00	
			13NOV2009	YES	7:00	YES	19:00	
			14NOV2009	YES	7:15	YES	19:00	
			15NOV2009	YES	8:00	YES	19:00	
			16NOV2009	YES	7:25	YES	19:00	
			17NOV2009	YES	7:30	YES	17:30	
			18NOV2009	YES	7:15			
			18NOV2009	YES	7:15	YES	19:15	
			19NOV2009	YES	7:45	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	20NOV2009	YES	7:15	YES	20:00	
			21NOV2009	YES	7:55	YES	20:00	
			22NOV2009	YES	7:45	YES	20:00	
			23NOV2009	YES	7:55	YES	20:00	
			24NOV2009	YES	7:55	YES	20:00	
			25NOV2009	YES	8:15	YES	19:00	
			26NOV2009	YES	8:00	YES	19:00	
			27NOV2009	YES	7:55	YES	19:55	
			28NOV2009	YES	8:00	YES	20:00	
			29NOV2009	YES	8:30	YES	19:00	
			30NOV2009	YES	8:30	YES	19:00	
			01DEC2009	YES	8:45	YES	19:55	
			02DEC2009	YES	10:00	YES	19:00	
			03DEC2009	YES	8:00	YES	19:30	
			04DEC2009	YES	7:45	YES	20:00	
			05DEC2009	YES	8:00			vergessen
			06DEC2009	YES	8:45	YES	19:00	
			07DEC2009	YES	8:45	YES	20:00	
			08DEC2009	YES	8:30	YES	17:45	
			09DEC2009	YES	8:00	YES	19:00	
			10DEC2009	YES	8:00	YES	19:00	
			11DEC2009	YES	7:30	YES	20:00	
			12DEC2009	YES	8:00	YES	19:00	
			13DEC2009	YES	8:30	YES	19:30	
			14DEC2009	YES	8:20	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	15DEC2009	YES	8:00	YES	20:00	
			16DEC2009	YES	8:00	YES	20:00	
			17DEC2009	YES	8:00	YES	18:30	
			18DEC2009	YES	8:05	YES	20:00	
			19DEC2009	YES	8:00	YES	18:20	
			20DEC2009	YES	8:15	YES	17:40	
			21DEC2009		7:50	YES	19:44	
			22DEC2009	YES	6:30	YES	19:10	
			23DEC2009	YES	7:45	YES	20:00	
			24DEC2009	YES	7:30		17:00	
			25DEC2009	YES	8:00	YES	20:00	
			26DEC2009	YES	6:55	YES	20:00	
			27DEC2009	YES	7:00	YES	20:00	
			28DEC2009	YES	7:40	YES	18:00	
			29DEC2009	YES	8:30	YES	17:45	
			30DEC2009	YES	7:55	YES	17:45	
			31DEC2009	YES	7:35	YES	18:00	
			01JAN2010	YES	8:00	YES	20:15	
			02JAN2010	YES	9:30	YES	18:00	
			03JAN2010	YES	8:40	YES	18:20	
			04JAN2010	YES	8:15	YES	18:40	
			05JAN2010	YES	8:40	YES	18:45	
			06JAN2010	YES	8:00	YES	18:00	
			07JAN2010	YES	7:00	YES	20:00	
			08JAN2010	YES	7:10	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	09JAN2010	YES	7:00	YES	18:30	
			10JAN2010	YES	8:00	YES	19:30	
			11JAN2010	YES	7:30	YES	21:00	
			12JAN2010	YES	7:30	YES	20:00	
			13JAN2010	YES	8:00	YES	17:45	
			14JAN2010	YES	7:30	YES	19:00	
			15JAN2010	YES	8:25	YES	19:00	
			16JAN2010	YES	8:30	YES	17:45	
			17JAN2010	YES	8:00	YES	19:00	
			18JAN2010	YES	8:00	YES	18:40	
			19JAN2010	YES	7:30	YES	20:00	
			20JAN2010	YES	8:00	YES	20:00	
			21JAN2010	YES	8:10	YES	18:00	
			22JAN2010	YES	8:00	YES	20:10	
			23JAN2010	YES	8:00	YES	19:00	
			24JAN2010	YES	8:15	YES	18:15	
			25JAN2010	YES	8:00	YES	20:20	
			26JAN2010	YES	7:45	YES	20:30	
			27JAN2010	YES	8:10	YES	18:00	
			28JAN2010	YES	8:10	YES	18:20	
			29JAN2010	YES	8:15	YES	19:45	
			30JAN2010	YES	7:15			vergessen
			31JAN2010	YES	8:30	YES	18:30	
			01FEB2010	YES	8:15	YES	20:20	
			02FEB2010	YES	7:30	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	03FEB2010	YES	8:00	YES	19:20	
			04FEB2010	YES	8:00	YES	18:00	
			05FEB2010	YES	8:00	YES	20:14	
			06FEB2010	YES	8:20	YES	18:00	
			07FEB2010	YES	7:40	YES	17:00	
			08FEB2010	YES	8:10	YES	18:30	
			09FEB2010	YES	8:00	YES	20:00	
			10FEB2010	YES	8:30	YES	18:00	
			11FEB2010	YES	8:10	YES	20:00	
			12FEB2010	YES	7:50	YES	20:00	
			13FEB2010	YES	8:15	YES	18:15	
			14FEB2010	YES	7:45	YES	19:00	
			15FEB2010	YES	8:00	YES	19:30	
			16FEB2010	YES	7:10			
			16FEB2010			YES	18:00	
			17FEB2010	YES	8:00	YES	19:45	
			18FEB2010	YES	7:30	YES	17:40	
			19FEB2010	YES	8:00	YES	17:30	
			20FEB2010	YES	7:30	YES	20:20	
			21FEB2010	YES	7:25	YES	19:00	
			22FEB2010	YES	8:00	YES	19:00	
			23FEB2010	YES	8:00	YES	20:00	
			24FEB2010	YES	7:30	YES	19:30	
			25FEB2010	YES	7:45	YES	20:00	
			26FEB2010	YES	7:45	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	27FEB2010	YES	7:00	YES	18:30	
			28FEB2010	YES	8:00	YES	18:30	
			01MAR2010	YES	8:00	YES	20:00	
			02MAR2010	YES	8:00	YES	20:00	
			03MAR2010	YES	8:00	YES	18:45	
			04MAR2010	YES	8:00	YES	18:00	
			05MAR2010	YES	7:30	YES	20:30	
			06MAR2010	YES	8:00	YES	18:45	
			07MAR2010	YES	7:30	YES	19:00	
			08MAR2010	YES	7:30	YES	20:00	
			09MAR2010	YES	7:30	YES	20:00	
			10MAR2010	YES	8:10	YES	19:30	
			11MAR2010	YES	8:00	YES	18:30	
			12MAR2010	YES	7:30	YES	19:55	
			13MAR2010	YES	7:45	YES	19:30	
			14MAR2010	YES	7:30	YES	19:00	
			15MAR2010	YES	7:40	YES	19:30	
			16MAR2010	YES	7:45	YES	20:50	
			17MAR2010	YES	7:15	YES	18:15	
			18MAR2010	YES	7:15	YES	19:00	
			19MAR2010	YES	7:45	YES	20:00	
			20MAR2010	YES	7:30	YES	18:30	
			21MAR2010	YES	7:45	YES	19:30	
			22MAR2010	YES	8:00	YES	19:30	
			23MAR2010	YES	7:15	YES	19:00	

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	24MAR2010	YES	7:30	YES	19:00	
			25MAR2010	YES	8:00	YES	19:15	
			26MAR2010	YES	7:30	YES	18:45	
			27MAR2010	YES	8:00	YES	20:00	
			28MAR2010	YES	8:00	YES	20:00	
			29MAR2010	YES	8:15	YES	20:00	
			30MAR2010	YES	8:00	YES	20:00	
			31MAR2010	YES	8:15	YES	20:00	
			01APR2010	YES	8:00	YES	20:15	
			02APR2010	YES	8:30	YES	20:00	
			03APR2010	YES	8:20	YES	20:00	
			04APR2010	YES	8:30	YES	19:30	
			05APR2010	YES	8:30	YES	19:45	
			06APR2010	YES	7:45	YES	20:00	
			07APR2010	YES	7:15	YES	20:00	
			08APR2010	YES	8:00	YES	20:00	
			09APR2010	YES	8:00	YES	20:00	
			10APR2010	YES	7:30	YES	20:10	
			11APR2010	YES	7:30	YES	19:00	
			12APR2010	YES	7:30	YES	19:00	
			13APR2010	YES	7:30	YES	20:00	
			14APR2010	YES	7:30	YES	20:00	
			15APR2010	YES	7:30	YES	20:00	
			16APR2010	YES	7:30	YES	20:00	
			17APR2010	YES	7:30	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	18APR2010	YES	7:45	YES	20:00	
			19APR2010	YES	8:30	YES	20:00	
			20APR2010	YES	8:00	YES	20:10	
			21APR2010	YES	8:00	YES	20:00	
			22APR2010	YES	7:30	YES	20:00	
			23APR2010	YES	7:30	YES	20:00	
			24APR2010	YES	7:00	YES	20:00	
			25APR2010	YES	7:30	YES	20:00	
			26APR2010	YES	7:30	YES	20:00	
			27APR2010	YES	7:30	YES	20:00	
			28APR2010	YES	8:00	YES	20:00	
			29APR2010	YES	8:00	YES	19:20	
			30APR2010	YES	8:00	YES	20:00	
			01MAY2010	YES	7:40	YES	20:00	
			02MAY2010	YES	7:30	YES	20:00	
			03MAY2010	YES	7:40	YES	19:45	
			04MAY2010	YES	7:30	YES	20:00	
			05MAY2010	YES	7:30	YES	20:00	
			06MAY2010	YES	7:25	YES	19:00	
			07MAY2010	YES	7:20	YES	20:05	
			08MAY2010	YES	7:00	YES	19:30	
			09MAY2010	YES	7:30	YES	20:40	
			10MAY2010	YES	9:00	YES	20:15	
			11MAY2010	YES	7:00	YES	20:00	
			12MAY2010	YES	8:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	005	2	13MAY2010	YES	7:30	YES	20:00	
			14MAY2010	YES	7:00	YES	20:00	
			15MAY2010	YES	7:00	YES	20:00	
			16MAY2010	YES	7:30	YES	20:00	
			17MAY2010	YES	7:10	YES	20:45	
			18MAY2010	YES	7:30	YES	20:00	
			19MAY2010	YES	7:00	YES	18:00	
			20MAY2010	YES	7:10	YES	18:00	
			21MAY2010	YES	7:00	YES	20:00	
			22MAY2010	YES	7:15	YES	18:30	
			23MAY2010	YES	7:25	YES	20:15	
			24MAY2010	YES	8:00	YES	19:30	
			25MAY2010	YES	7:20	YES	19:30	
			26MAY2010	YES	8:00	YES	19:30	
			27MAY2010	YES	7:45			vergessen!!!
			28MAY2010	YES	11:45	YES	19:45	
			29MAY2010	YES	7:50	YES	19:30	
			30MAY2010	YES	7:55	YES	20:15	
			31MAY2010	YES	8:00	YES	20:10	
			01JUN2010	YES	7:10	YES	20:00	
			02JUN2010	YES	7:30			
	009	1	27MAY1940	YES	7:15	YES	16:50	
			09SEP2009	YES	8:30	YES	7:00	
			10SEP2009	YES	8:00	YES	6:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	11SEP2009	YES	7:50	YES	6:55	
			12SEP2009	YES	8:10	YES	19:00	
			13SEP2009	YES	8:15	YES	20:30	
			14SEP2009	YES	7:55	YES	20:45	
			15SEP2009	YES	9:00	YES	20:25	
			16SEP2009	YES	8:10	YES	18:20	
			17SEP2009	YES	8:35	YES	18:30	
			18SEP2009	YES	8:20	YES	19:05	
			19SEP2009	YES	7:15	YES	19:20	
			20SEP2009	YES	8:10	YES	18:50	
			21SEP2009	YES	7:45	YES	19:00	
			22SEP2009	YES	8:00	YES	18:50	
			23SEP2009	YES	6:45	YES	19:00	
			24SEP2009	YES	8:15	YES	19:10	
			25SEP2009	YES	7:45	YES	20:00	
			26SEP2009	YES	8:00	YES	18:50	
			27SEP2009	YES	7:10	YES	18:10	
			28SEP2009	YES	7:30	YES	18:00	
			29SEP2009	YES	7:15	YES	18:45	
			30SEP2009	YES	7:45	YES	19:00	
			01OCT2009	YES	7:50	YES	18:50	
			02OCT2009	YES	7:20	YES	19:10	
			03OCT2009	YES	8:00	YES	19:50	
			04OCT2009	YES	8:15	YES	20:00	
			05OCT2009	YES	7:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	06OCT2009	YES	8:00	YES	18:30	
			07OCT2009	YES	7:00			
			07OCT2009			YES	19:00	
			08OCT2009	YES	7:45	YES	18:45	
			09OCT2009	YES	7:30	YES	19:30	
			10OCT2009	YES	8:00	YES	18:50	
			11OCT2009	YES	8:10	YES	19:00	
			16OCT2009	YES	8:15	YES	18:15	
			17OCT2009	YES	8:00	YES	18:00	
			18OCT2009	YES	8:00	YES	18:30	
			19OCT2009	YES	6:45	YES	18:45	
			20OCT2009	YES	7:00	YES	18:00	
			21OCT2009	YES	7:15	YES	18:30	
			22OCT2009	YES	7:40	YES	18:10	
			23OCT2009	YES	7:00	YES	18:00	
			24OCT2009	YES	7:20	YES	17:50	
			25OCT2009	YES	8:15	YES	17:45	
			26OCT2009	YES	7:30	YES	18:00	
			27OCT2009	YES	7:30	YES	18:15	
			28OCT2009	YES	8:00	YES	19:00	
			29OCT2009	YES	8:15	YES	18:45	
			30OCT2009	YES	8:00	YES	18:30	
			31OCT2009	YES	7:50	YES	18:00	
			01NOV2009	YES	7:00	YES	18:20	
			02NOV2009	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	03NOV2009	YES	6:50	YES	18:00	
			04NOV2009	YES	7:15	YES	18:30	
			05NOV2009	YES	7:30	YES	18:15	
			06NOV2009	YES	6:30	YES	19:30	
			07NOV2009	YES	8:00	YES	18:00	
			08NOV2009	YES	7:50	YES	17:30	
			09NOV2009	YES	8:15	YES	17:00	
			10NOV2009	YES	8:05	YES	17:30	
			11NOV2009	YES	8:00	YES	17:15	
			12NOV2009	YES	7:15	YES	19:00	
			12NOV2009	YES	8:30	YES	18:00	
			13NOV2009	YES	7:45	YES	19:15	
			13NOV2009	YES	7:45	YES	18:15	
			14NOV2009	YES	7:00	YES	18:45	
			14NOV2009	YES	7:00	YES	17:50	
			15NOV2009	YES	8:10	YES	19:00	
			15NOV2009	YES	7:20	YES	18:10	
			16NOV2009	YES	8:00	YES	17:45	
			17NOV2009	YES	8:15	YES	17:00	
			18NOV2009	YES	8:00	YES	18:00	
			19NOV2009	YES	8:00	YES	17:30	
			20NOV2009	YES	7:30	YES	17:30	
			21NOV2009	YES	8:30	YES	17:50	
			22NOV2009	YES	8:15	YES	17:30	
			23NOV2009	YES	8:00	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	24NOV2009	YES	8:00	YES	18:00	
			25NOV2009	YES	7:30	YES	18:00	
			26NOV2009	YES	6:45	YES	18:30	
			27NOV2009	YES	7:00	YES	17:50	
			28NOV2009	YES	7:00	YES	18:10	
			29NOV2009	YES	7:30	YES	18:15	
			30NOV2009	YES	8:00	YES	17:50	
			01DEC2009	YES	8:00	YES	18:00	
			02DEC2009	YES	8:00	YES	18:15	
			03DEC2009	YES	7:50	YES	18:50	
			04DEC2009	YES	7:30	YES	18:00	
			05DEC2009	YES	7:00	YES	19:30	
			06DEC2009	YES	8:30	YES	17:45	
			07DEC2009	YES	8:45	YES	17:30	
			08DEC2009	YES	7:30	YES	18:00	
			09DEC2009	YES	7:30	YES	7:30	
			10DEC2009	YES	6:30			
			10DEC2009			YES	19:30	
			11DEC2009	YES	8:00		17:30	
			12DEC2009	YES	7:45	YES	18:15	
			13DEC2009	YES	8:00	YES	18:30	
			14DEC2009	YES	7:50	YES	19:00	
			15DEC2009	YES	8:10	YES	19:10	
			16DEC2009	YES	7:45	YES	18:45	
			17DEC2009	YES	8:00	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	18DEC2009	YES	8:00	YES	17:30	
			19DEC2009	YES	7:30	YES	18:00	
			20DEC2009	YES	8:00	YES	17:30	
			21DEC2009	YES	7:50	YES	17:45	
			22DEC2009	YES	7:00	YES	18:10	
			23DEC2009	YES	7:45	YES	18:20	
			24DEC2009	YES	7:30	YES	18:00	
			25DEC2009	YES	8:00	YES	18:00	
			26DEC2009	YES	8:10	YES	18:00	
			27DEC2009	YES	8:00	YES	17:30	
			28DEC2009	YES	8:00	YES	17:30	
			29DEC2009	YES	7:30	YES	18:00	
			30DEC2009	YES	8:15		17:50	
			31DEC2009	YES	8:30	YES	18:30	
			01JAN2010	YES	8:00	YES	18:00	
			02JAN2010	YES	7:30	YES	17:15	
			03JAN2010	YES	7:00	YES	17:45	
			04JAN2010	YES	7:45	YES	18:00	
			05JAN2010	YES	7:00	YES	18:30	
			06JAN2010	YES	8:15	YES	18:15	
			07JAN2010	YES	8:00	YES	18:00	
			08JAN2010	YES	8:30	YES	18:30	
			09JAN2010	YES	8:15	YES	18:00	
			10JAN2010	YES	8:15	YES	18:45	
			11JAN2010	YES	8:15	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	12JAN2010	YES	7:45	YES	18:00	
			13JAN2010	YES	8:00	YES	17:15	
			14JAN2010	YES	8:30	YES	17:15	
			15JAN2010	YES	7:50	YES	17:45	
			16JAN2010	YES	8:30	YES	18:10	
			17JAN2010	YES	8:15	YES	18:30	
			18JAN2010	YES	8:00	YES	18:00	
			19JAN2010	YES	8:00	YES	18:30	
			20JAN2010	YES	8:30	YES	18:15	
			21JAN2010	YES	7:50	YES	18:15	
			22JAN2010	YES	8:00	YES	18:30	
			23JAN2010	YES	8:00	YES	18:15	
			24JAN2010	YES	8:15	YES	18:30	
			25JAN2010	YES	7:45	YES	17:15	
			26JAN2010	YES	8:00	YES	17:30	
			27JAN2010	YES	8:30	YES	17:45	
			28JAN2010	YES	7:45	YES	17:45	
			29JAN2010	YES	7:30	YES	18:00	
			30JAN2010	YES	8:00	YES	18:30	
			31JAN2010	YES	8:00	YES	18:30	
			01FEB2010	YES	8:15		18:00	
			02FEB2010	YES	8:00	YES	17:45	
			03FEB2010	YES	7:50	YES	18:00	
			04FEB2010	YES	8:00	YES	18:15	
			05FEB2010	YES	8:00		17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	06FEB2010	YES	8:15	YES	19:00	
			07FEB2010	YES	8:30	YES	19:15	
			08FEB2010	YES	8:00	YES	19:00	
			09FEB2010	YES	8:10	YES	18:50	
			10FEB2010	YES	7:50	YES	18:00	
			11FEB2010	YES	8:15	YES	19:00	
			12FEB2010	YES	7:30	YES	19:15	
			13FEB2010	YES	7:30	YES	18:45	
			14FEB2010	YES	7:00	YES	18:30	
			15FEB2010	YES	7:15	YES	19:00	
			16FEB2010	YES	7:00	YES	18:45	
			17FEB2010	YES	8:00	YES	18:30	
			18FEB2010	YES	7:45	YES	18:15	
			19FEB2010	YES	7:30	YES	19:00	
			20FEB2010	YES	8:15	YES	18:15	
			21FEB2010	YES	8:30	YES	18:00	
			22FEB2010	YES	8:00	YES	18:00	
			23FEB2010	YES	7:30	YES	17:50	
			24FEB2010	YES	7:30	YES	17:30	
			25FEB2010	YES	8:15	YES	17:00	
			26FEB2010	YES	7:45	YES	18:00	
			27FEB2010	YES	8:00	YES	18:00	
			28FEB2010	YES	8:00	YES	18:00	
			01MAR2010	YES	8:15	YES	18:15	
			02MAR2010	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	03MAR2010	YES	7:45	YES	18:30	
			04MAR2010	YES	8:00			
			04MAR2010			YES	17:30	
			05MAR2010	YES	8:00	YES	17:30	
			06MAR2010	YES	7:50	YES	18:00	
			07MAR2010	YES	7:30	YES	18:00	
			08MAR2010	YES	7:45	YES	17:45	
			09MAR2010	YES	8:15	YES	18:10	
			10MAR2010	YES	8:00	YES	17:00	
			11MAR2010	YES	7:50	YES	17:30	
			12MAR2010	YES	7:00	YES	18:00	
			13MAR2010	YES	8:00	YES	17:50	
			14MAR2010	YES	8:00	YES	17:30	
			15MAR2010	YES	8:15	YES	17:15	
			16MAR2010	YES	7:30	YES	18:00	
			17MAR2010	YES	7:00	YES	18:30	
			18MAR2010	YES	8:50	YES	18:15	
			19MAR2010	YES	7:30	YES	18:00	
			20MAR2010	YES	8:00	YES	18:00	
			21MAR2010	YES	7:50	YES	17:30	
			22MAR2010	YES	8:15	YES	17:30	
			23MAR2010	YES	7:40	YES	17:00	
			24MAR2010	YES	7:30	YES	17:45	
			25MAR2010	YES	7:00	YES	18:00	
			26MAR2010	YES	7:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	27MAR2010	YES	7:30	YES	18:50	
			28MAR2010	YES	8:00	YES	17:50	
			29MAR2010	YES	8:15	YES	18:10	
			30MAR2010	YES	7:40	YES	17:50	
			31MAR2010	YES	7:50	YES	19:00	
			01APR2010	YES	8:15	YES	18:30	
			02APR2010	YES	8:30	YES	18:20	
			03APR2010	YES	8:10	YES	17:30	
			04APR2010	YES	8:30	YES	17:10	
			05APR2010	YES	7:00	YES	18:00	
			06APR2010	YES	7:00	YES	18:00	
			07APR2010	YES	7:15	YES	18:00	
			08APR2010	YES	7:30	YES	17:50	
			09APR2010	YES	8:00	YES	17:50	
			10APR2010	YES	8:10	YES	17:30	
			11APR2010	YES	8:00	YES	18:00	
			12APR2010	YES	8:15	YES	17:45	
			13APR2010	YES	7:30	YES	17:30	
			14APR2010	YES	7:45	YES	17:10	
			15APR2010	YES	7:00	YES	18:10	
			16APR2010	YES	8:00	YES	18:30	
			17APR2010	YES	8:15	YES	18:10	
			18APR2010	YES	7:50	YES	18:00	
			19APR2010	YES	8:00	YES	17:50	
			20APR2010	YES	8:00	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	21APR2010	YES	7:45	YES	18:10	
			22APR2010	YES	7:00	YES	18:00	
			23APR2010	YES	7:30	YES	17:30	
			24APR2010	YES	8:15	YES	18:00	
			25APR2010	YES	7:50	YES	17:50	
			26APR2010	YES	8:15	YES	17:45	
			27APR2010	YES	7:50	YES	18:10	
			28APR2010	YES	7:45	YES	17:50	
			29APR2010	YES	7:30	YES	17:45	
			30APR2010	YES	8:10	YES	18:00	
			01MAY2010	YES	7:50	YES	17:45	
			02MAY2010	YES	7:00	YES	17:30	
			03MAY2010	YES	8:10	YES	17:50	
			04MAY2010	YES	7:50	YES	18:00	
			05MAY2010	YES	8:00	YES	18:00	
			06MAY2010	YES	7:00	YES	18:00	
			07MAY2010	YES	8:00	YES	18:00	
			08MAY2010	YES	8:15	YES	18:00	
			09MAY2010	YES	7:50	YES	17:30	
			10MAY2010	YES	8:10	YES	18:10	
			11MAY2010		6:30			
			11MAY2010			YES	19:00	
			12MAY2010	YES	8:00	YES	18:15	
			13MAY2010	YES	7:50	YES	18:00	
			14MAY2010	YES	8:00	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	15MAY2010	YES	7:30	YES	18:15	
			16MAY2010	YES	7:30	YES	18:15	
			17MAY2010	YES	7:50	YES	17:50	
			18MAY2010	YES	8:00	YES	18:00	
			19MAY2010	YES	8:10	YES	18:50	
			20MAY2010	YES	8:00	YES	19:00	
			21MAY2010	YES	7:50	YES	18:00	
			22MAY2010	YES	8:00	YES	19:10	
			23MAY2010	YES	7:50	YES	18:20	
			24MAY2010	YES	7:30	YES	18:00	
			25MAY2010	YES	8:15	YES	18:30	
			26MAY2010	YES	7:30	YES	17:50	
			28MAY2010	YES	7:00	YES	18:00	
			29MAY2010	YES	7:50	YES	18:15	
			30MAY2010	YES	8:00		17:30	
			31MAY2010	YES	7:50	YES	18:10	
			01JUN2010	YES	8:10	YES	18:15	
			02JUN2010	YES	8:00	YES	17:50	
			03JUN2010	YES	7:50	YES	17:45	
			04JUN2010	YES	8:00	YES	18:00	
			05JUN2010	YES	7:50	YES	17:50	
			06JUN2010	YES	8:10	YES	17:45	
			07JUN2010	YES	8:15	YES	17:50	
			08JUN2010	YES	7:50	YES	17:30	
			09JUN2010	YES	7:45	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	10JUN2010	YES	8:00	YES	17:45	
			11JUN2010	YES	7:50	YES	17:25	
			12JUN2010	YES	8:10	YES	18:00	
			13JUN2010	YES	8:00	YES	17:50	
			14JUN2010	YES	8:00	YES	17:30	
			15JUN2010	YES	7:45	YES	18:00	
			16JUN2010	YES	8:00	YES	17:30	
			17JUN2010	YES	7:50	YES	18:00	
			18JUN2010	YES	7:30	YES	17:50	
			19JUN2010	YES	8:10	YES	17:30	
			20JUN2010	YES	7:45	YES	18:00	
			21JUN2010	YES	7:50	YES	17:45	
			22JUN2010	YES	8:10	YES	18:15	
			23JUN2010	YES	8:00	YES	17:30	
			24JUN2010	YES	7:40	YES	17:45	
			25JUN2010	YES	8:15	YES	18:00	
			26JUN2010	YES	7:50	YES	18:00	
			27JUN2010	YES	8:00	YES	18:10	
			28JUN2010	YES	8:00	YES	18:00	
			29JUN2010	YES	7:30	YES	18:30	
			30JUN2010	YES	7:00	YES	17:35	
			01JUL2010	YES	8:10	YES	18:00	
			02JUL2010	YES	7:45	YES	18:00	
			03JUL2010	YES	7:00	YES	19:00	
			04JUL2010	YES	8:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	05JUL2010	YES	7:50	YES	17:50	
			06JUL2010	YES	7:00	YES	18:00	
			07JUL2010	YES	7:00	YES	18:10	
			08JUL2010	YES	7:20	YES	18:00	
			09JUL2010	YES	8:00	YES	17:50	
			10JUL2010	YES	7:50	YES	17:30	
			11JUL2010	YES	7:00	YES	17:10	
			12JUL2010	YES	8:00		18:00	
			13JUL2010	YES	8:10	YES	17:30	
			14JUL2010	YES	7:50	YES	18:00	
			15JUL2010	YES	7:45	YES	18:00	
			16JUL2010	YES	7:30	YES	18:00	
			17JUL2010	YES	8:00		17:30	
			18JUL2010	YES	8:00		18:00	
			19JUL2010	YES	8:00		18:20	
			20JUL2010	YES	7:50	YES	17:30	
			21JUL2010	YES	8:00	YES	18:10	
			22JUL2010	YES	7:45	YES	18:00	
			23JUL2010	YES	8:00	YES	18:00	
			24JUL2010	YES	7:50	YES	17:50	
			25JUL2010	YES	8:00	YES	18:10	
			26JUL2010	YES	7:30	YES	17:50	
			27JUL2010	YES	7:50	YES	18:00	
			28JUL2010	YES	8:10	YES	17:45	
			29JUL2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	30JUL2010	YES	7:50	YES	17:30	
			31JUL2010	YES	8:00	YES	17:30	
			01AUG2010	YES	7:20	YES	18:10	
			02AUG2010	YES	8:10	YES	17:45	
			03AUG2010	YES	8:00	YES	18:00	
			04AUG2010	YES	7:50	YES	18:00	
			05AUG2010	YES	7:30	YES	18:10	
			06AUG2010	YES	8:15	YES	18:00	
			07AUG2010	YES	8:00	YES	18:00	
			08AUG2010	YES	7:30	YES	17:50	
			09AUG2010	YES	7:50	YES	18:00	
			10AUG2010	YES	8:00	YES	17:50	
			11AUG2010	YES	8:00	YES	17:30	
			12AUG2010	YES	7:50	YES	18:00	
			13AUG2010	YES	7:45	YES	18:10	
			14AUG2010	YES	8:10	YES	17:50	
			15AUG2010	YES	8:15	YES	18:30	
			16AUG2010	YES	7:50	YES	17:45	
			17AUG2010	YES	7:30	YES	18:00	
			18AUG2010	YES	7:45	YES	18:30	
			19AUG2010	YES	8:00	YES	19:00	
			20AUG2010	YES	7:50	YES	19:20	
			21AUG2010	YES	7:00	YES	18:30	
			22AUG2010	YES	8:15	YES	18:15	
			23AUG2010	YES	8:00	YES	17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	009	1	24AUG2010	YES	8:00	YES	17:30	
			25AUG2010	YES	8:00	YES	18:00	
			26AUG2010	YES	7:30	YES	18:00	
			27AUG2010	YES	7:30	YES	17:30	
			28AUG2010	YES	7:50	YES	17:30	
			29AUG2010	YES	7:30	YES	18:00	
			30AUG2010	YES	8:00	YES	18:15	
			31AUG2010	YES	7:50	YES	17:50	
			01SEP2010	YES	8:00	YES	18:00	
			02SEP2010	YES	7:30	YES	18:00	
			03SEP2010	YES	6:45			
	011	1	06NOV2000	YES	8:30	YES	17:00	
			26NOV2009			YES	18:00	Beginn der Therapie
			27NOV2009	YES	8:00	YES	17:30	
			28NOV2009	YES	7:30	YES	17:15	
			29NOV2009	YES	8:30	YES	16:50	
			30NOV2009	YES	8:15	YES	17:10	
			01DEC2009	YES	8:00	YES	17:00	
			02DEC2009	YES	8:20	YES	17:30	
			03DEC2009	YES	7:50	YES	17:30	
			04DEC2009	YES	8:00	YES	17:15	
			05DEC2009	YES	8:30	YES	17:30	
			06DEC2009	YES	8:00	YES	17:00	
			07DEC2009	YES	7:50	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	08DEC2009	YES	7:30	YES	17:30	
			09DEC2009	YES	8:00	YES	17:30	
			10DEC2009	YES	8:30	YES	18:00	
			11DEC2009	YES	8:15	YES	17:30	
			12DEC2009	YES	7:40	YES	17:20	
			13DEC2009	YES	8:30	YES	17:10	
			14DEC2009	YES	8:00	YES	17:20	
			15DEC2009	YES	8:10	YES	17:40	
			16DEC2009	YES	8:30	YES	17:30	
			17DEC2009	YES	8:20	YES	17:00	
			18DEC2009	YES	8:20	YES	18:00	
			19DEC2009	YES	8:00	YES	17:00	
			20DEC2009	YES	8:30	YES	17:00	
			21DEC2009	YES	8:20	YES	17:30	
			22DEC2009	YES	8:30	YES	17:20	
			23DEC2009	YES	8:20	YES	17:10	
			24DEC2009	YES	8:30	YES	18:30	
			25DEC2009	YES	8:30	YES	17:00	
			26DEC2009	YES	8:15	YES	18:30	
			27DEC2009	YES	9:00	YES	17:40	
			28DEC2009	YES	8:10	YES	17:10	
			29DEC2009	YES	8:20	YES	17:30	
			30DEC2009	YES	8:00			
			30DEC2009			YES	18:00	
			31DEC2009	YES	8:00	YES	17:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	01JAN2010	YES	8:30	YES	17:00	
			02JAN2010	YES	8:20	YES	17:30	
			03JAN2010	YES	8:30	YES	17:00	
			04JAN2010	YES	8:20	YES	17:30	
			05JAN2010	YES	8:30	YES	17:15	
			06JAN2010	YES	8:00	YES	18:30	1 Tablette unter Couch gefallen, neue Tablette genommen-18.2.10 Sax
			07JAN2010	YES	8:20	YES	17:10	
			08JAN2010	YES	8:30	YES	17:20	
			09JAN2010	YES	8:00	YES	17:30	
			10JAN2010	YES	8:30	YES	17:30	
			11JAN2010	YES	8:00	YES	17:10	Zahnarzt
			12JAN2010	YES	8:20	YES	18:00	Zahnarzt
			13JAN2010	YES	8:00	YES	17:00	Zahnarzt
			14JAN2010	YES	8:30	YES	17:15	
			15JAN2010	YES	8:10	YES	17:10	
			16JAN2010	YES	8:00	YES	17:30	
			17JAN2010	YES	8:00	YES	17:00	
			18JAN2010	YES	7:50	YES	17:00	
			19JAN2010	YES	8:30	YES	18:00	
			20JAN2010	YES	8:00	YES	18:30	
			21JAN2010	YES	7:50	YES	17:00	
			22JAN2010	YES	8:15	YES	17:00	
			23JAN2010	YES	8:30	YES	17:15	
			24JAN2010	YES	8:00	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	25JAN2010	YES	7:30	YES	17:00	
			26JAN2010	YES	8:15	YES	18:00	
			27JAN2010	YES	8:30	YES	18:15	
			28JAN2010	YES	8:00	YES	17:15	
			29JAN2010	YES	8:30	YES	17:00	
			30JAN2010	YES	8:20	YES	17:10	
			31JAN2010	YES	8:30	YES	17:00	
			01FEB2010	YES	8:00	YES	17:30	
			02FEB2010	YES	8:30	YES	17:30	
			03FEB2010	YES	8:00	YES	17:20	
			04FEB2010	YES	8:20	YES	17:20	
			05FEB2010	YES	8:00	YES	17:30	
			06FEB2010	YES	8:30	YES	17:30	
			07FEB2010	YES	8:15	YES	18:00	
			08FEB2010	YES	8:30	YES	17:45	
			09FEB2010	YES	7:40	YES	17:30	
			10FEB2010	YES	8:10	YES	17:10	
			11FEB2010	YES	8:10	YES	17:20	
			12FEB2010	YES	8:00	YES	17:30	
			13FEB2010	YES	7:50	YES	17:15	
			14FEB2010	YES	8:00	YES	17:00	
			15FEB2010	YES	8:30	YES	17:20	
			16FEB2010	YES	8:10	YES	17:30	
			17FEB2010	YES	8:00	YES	17:40	
			18FEB2010	YES	7:50			

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	18FEB2010			YES	17:30	
			19FEB2010	YES	8:00	YES	17:45	
			20FEB2010	YES	7:50	YES	17:50	
			21FEB2010	YES	8:15	YES	17:00	
			22FEB2010	YES	8:00	YES	17:15	
			23FEB2010	YES	8:15	YES	17:20	
			24FEB2010	YES	8:20	YES	17:45	
			25FEB2010	YES	7:30	YES	17:30	
			26FEB2010	YES	7:10	YES	17:10	
			27FEB2010	YES	8:00	YES	17:00	
			28FEB2010	YES	8:15	YES	17:20	
			01MAR2010	YES	8:30	YES	17:00	
			02MAR2010	YES	8:20	YES	17:30	
			03MAR2010	YES	8:00	YES	17:10	
			04MAR2010	YES	8:30	YES	17:15	
			05MAR2010	YES	8:15	YES	17:15	
			06MAR2010	YES	8:00	YES	17:45	
			07MAR2010	YES	8:30	YES	17:30	
			08MAR2010	YES	8:00		17:15	
			09MAR2010	YES	8:20	YES	17:30	
			10MAR2010	YES	8:30	YES	17:20	
			11MAR2010	YES	8:00	YES	18:00	
			12MAR2010	YES	8:10	YES	17:30	
			13MAR2010	YES	8:00	YES	18:00	
			14MAR2010	YES	8:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	15MAR2010	YES	8:15	YES	17:10	
			16MAR2010	YES	7:45	YES	17:30	
			17MAR2010	YES	8:00	YES	17:30	
			18MAR2010	YES	7:50	YES	17:00	
			19MAR2010	YES	8:20	YES	17:40	
			20MAR2010	YES	8:00	YES	17:30	
			21MAR2010	YES	7:45	YES	17:40	
			22MAR2010	YES	8:00	YES	17:30	
			23MAR2010	YES	8:00	YES	17:40	
			24MAR2010	YES	8:10	YES	17:30	
			25MAR2010	YES	7:50	YES	17:50	
			26MAR2010	YES	8:00	YES	17:45	
			27MAR2010	YES	8:20	YES	17:30	
			28MAR2010	YES	8:20	YES	17:20	Zeitumstellung
			29MAR2010	YES	8:10	YES	18:00	
			30MAR2010	YES	8:00	YES	17:30	
			31MAR2010	YES	8:30	YES	17:20	
			01APR2010	YES	8:00	YES	17:30	
			02APR2010	YES	8:15	YES	17:15	
			03APR2010	YES	8:30	YES	17:30	
			04APR2010	YES	8:30	YES	17:30	
			05APR2010	YES	8:20	YES	17:15	
			06APR2010	YES	8:20	YES	17:00	
			07APR2010	YES	8:15	YES	17:30	
			08APR2010	YES	8:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	09APR2010	YES	8:00	YES	17:30	
			10APR2010	YES	8:30	YES	17:15	
			11APR2010	YES	8:00	YES	17:00	
			12APR2010	YES	8:15	YES	17:00	
			13APR2010	YES	8:00	YES	17:45	
			14APR2010	YES	8:30	YES	17:30	
			15APR2010	YES	8:20	YES	17:30	
			16APR2010	YES	8:00		17:30	
			17APR2010	YES	8:15	YES	17:15	
			18APR2010	YES	8:20	YES	17:00	
			19APR2010	YES	8:10	YES	17:10	
			20APR2010	YES	8:30	YES	17:30	
			21APR2010	YES	8:15	YES	17:00	
			22APR2010	YES	8:30	YES	17:30	
			23APR2010	YES	8:15	YES	17:00	
			24APR2010	YES	8:00	YES	17:30	
			25APR2010	YES	8:15	YES	17:00	
			26APR2010	YES	8:30	YES	17:00	
			27APR2010	YES	8:00	YES	17:00	
			28APR2010	YES	8:15	YES	17:10	
			29APR2010	YES	7:30	YES	17:20	
			30APR2010		8:00	YES	17:30	
			01MAY2010	YES	8:30	YES	18:00	
			02MAY2010	YES	8:20	YES	17:50	
			03MAY2010	YES	8:30	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	04MAY2010	YES	8:10	YES	17:40	
			05MAY2010	YES	8:20	YES	17:30	
			06MAY2010	YES	8:10			
			06MAY2010			YES	19:30	Späte Ankunft aus München
			07MAY2010	YES	8:00	YES	17:00	
			08MAY2010	YES	7:40	YES	17:30	
			09MAY2010	YES	8:10	YES	17:10	
			10MAY2010	YES	8:00	YES	17:00	
			11MAY2010	YES	7:45	YES	17:30	
			12MAY2010	YES	8:00	YES	17:30	
			13MAY2010	YES	8:10	YES	17:45	
			14MAY2010	YES	8:15	YES	17:10	
			15MAY2010	YES	8:15	YES	17:00	
			16MAY2010	YES	8:30	YES	17:10	
			17MAY2010	YES	8:20	YES	17:25	
			18MAY2010	YES	8:10	YES	17:30	
			19MAY2010	YES	8:00	YES	17:15	
			20MAY2010	YES	7:30	YES	17:10	
			21MAY2010	YES	7:45	YES	17:30	
			22MAY2010	YES	8:00	YES	17:50	
			23MAY2010	YES	8:10	YES	17:30	
			24MAY2010	YES	8:10	YES	17:45	
			25MAY2010	YES	8:20	YES	17:30	
			26MAY2010	YES	8:10	YES	18:00	
			27MAY2010	YES	7:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	28MAY2010	YES	8:00	YES	17:15	
			29MAY2010	YES	8:30	YES	17:40	
			30MAY2010	YES	8:30	YES	17:00	
			31MAY2010	YES	8:20	YES	17:30	
			01JUN2010	YES	8:30	YES	17:10	
			02JUN2010	YES	8:20	YES	17:00	
			03JUN2010	YES	8:30	YES	17:15	
			04JUN2010	YES	8:20	YES	17:30	
			05JUN2010	YES	8:00	YES	17:20	
			06JUN2010	YES	8:20	YES	17:30	
			07JUN2010	YES	8:00	YES	17:00	
			08JUN2010	YES	8:20	YES	17:30	
			09JUN2010	YES	8:10	YES	17:30	
			10JUN2010	YES	8:30	YES	17:40	
			11JUN2010	YES	8:00	YES	17:20	
			12JUN2010	YES	8:10	YES	17:10	
			13JUN2010	YES	8:15	YES	17:00	
			14JUN2010	YES	8:00	YES	17:10	
			15JUN2010	YES	8:20	YES	17:00	
			16JUN2010	YES	8:30	YES	17:15	
			17JUN2010	YES	8:10	YES	17:00	
			18JUN2010	YES	8:30	YES	17:10	
			19JUN2010	YES	8:20	YES	17:00	
			20JUN2010	YES	8:30	YES	17:00	
			21JUN2010	YES	8:10	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	22JUN2010	YES	8:20	YES	17:00	
			23JUN2010	YES	8:00	YES	17:00	
			24JUN2010	YES	8:30	YES	17:30	
			25JUN2010	YES	8:20	YES	17:20	
			26JUN2010	YES	8:10	YES	17:00	
			27JUN2010	YES	8:30	YES	17:00	
			28JUN2010	YES	8:20	YES	17:10	
			29JUN2010	YES	8:20	YES	17:30	
			30JUN2010	YES	8:10	YES	17:00	
			01JUL2010	YES	8:00	YES	17:10	
			02JUL2010	YES	7:50	YES	17:30	
			03JUL2010	YES	8:20	YES	17:00	
			04JUL2010	YES	8:00	YES	17:00	
			05JUL2010	YES	8:15	YES	17:20	
			06JUL2010	YES	8:00	YES	17:30	
			07JUL2010	YES	8:20	YES	17:30	
			08JUL2010	YES	8:20	YES	17:00	
			09JUL2010	YES	8:00	YES	17:15	
			10JUL2010	YES	8:15	YES	17:00	
			11JUL2010	YES	8:10	YES	17:00	
			12JUL2010	YES	8:20	YES	17:00	
			13JUL2010	YES	8:00	YES	17:30	
			14JUL2010	YES	8:20	YES	17:00	
			15JUL2010	YES	8:10	YES	17:20	
			16JUL2010	YES	8:20	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	17JUL2010	YES	8:30	YES	17:20	
			18JUL2010	YES	8:10	YES	17:00	
			19JUL2010	YES	8:00	YES	17:00	
			20JUL2010	YES	7:50	YES	17:00	
			21JUL2010	YES	8:10	YES	16:45	
			22JUL2010	YES	8:20	YES	17:00	
			23JUL2010	YES	8:30	YES	17:10	
			24JUL2010	YES	8:10	YES	17:30	
			25JUL2010	YES	8:20	YES	17:30	
			26JUL2010	YES	7:45	YES	17:00	
			27JUL2010	YES	8:00	YES	17:00	
			28JUL2010	YES	8:20	YES	17:10	
			29JUL2010	YES	8:10	YES	17:00	
			30JUL2010	YES	8:00	YES	17:10	
			31JUL2010	YES	8:20	YES	17:00	
			01AUG2010	YES	8:10	YES	17:00	
			02AUG2010	YES	8:00	YES	17:00	
			03AUG2010	YES	8:20	YES	17:00	
			04AUG2010	YES	8:30	YES	17:30	
			05AUG2010	YES	7:00			
			05AUG2010			YES	18:00	
			06AUG2010	YES	7:50	YES	17:30	
			07AUG2010	YES	8:00	YES	17:30	
			08AUG2010	YES	8:20	YES	17:00	
			09AUG2010	YES	8:10	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	10AUG2010	YES	8:20	YES	17:20	
			11AUG2010	YES	8:00	YES	17:30	
			12AUG2010	YES	7:30	YES	17:20	
			13AUG2010	YES	8:15	YES	17:00	
			14AUG2010	YES	8:00	YES	17:20	
			15AUG2010	YES	8:20	YES	17:30	
			16AUG2010	YES	8:10	YES	17:00	
			17AUG2010	YES	8:30	YES	17:00	
			18AUG2010	YES	8:30	YES	18:30	
			19AUG2010	YES	8:20	YES	17:00	
			20AUG2010	YES	8:00	YES	18:00	
			21AUG2010	YES	8:10	YES	17:30	
			22AUG2010	YES	8:30	YES	17:15	
			23AUG2010	YES	8:10	YES	17:30	
			24AUG2010	YES	8:00	YES	17:00	
			25AUG2010	YES	8:20	YES	18:00	
			26AUG2010	YES	8:30	YES	17:00	
			27AUG2010	YES	8:10	YES	17:00	
			28AUG2010	YES	8:30	YES	17:00	
			29AUG2010	YES	8:20	YES	17:00	
			30AUG2010	YES	8:30	YES	17:10	
			31AUG2010	YES	8:00	YES	17:00	
			01SEP2010	YES	8:00	YES	17:30	
			02SEP2010	YES	8:10	YES	17:00	
			03SEP2010	YES	8:20	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	04SEP2010	YES	8:00	YES	17:00	
			05SEP2010	YES	8:30	YES	17:15	
			06SEP2010	YES	8:10	YES	17:00	
			07SEP2010	YES	8:20	YES	17:00	
			08SEP2010	YES	8:15	YES	17:00	
			09SEP2010	YES	8:20	YES	17:00	
			10SEP2010	YES	8:30	YES	17:30	
			11SEP2010	YES	8:20	YES	17:10	
			12SEP2010	YES	8:30	YES	17:20	
			13SEP2010	YES	8:10	YES	17:00	
			14SEP2010	YES	8:10	YES	17:00	
			15SEP2010	YES	8:30	YES	17:00	
			16SEP2010	YES	8:15	YES	17:20	
			17SEP2010	YES	8:00	YES	17:00	
			18SEP2010	YES	8:30	YES	17:30	
			19SEP2010	YES	8:10	YES	17:00	
			20SEP2010	YES	8:30	YES	17:20	
			21SEP2010	YES	8:20	YES	17:30	
			22SEP2010	YES	8:30	YES	17:00	
			23SEP2010	YES	8:20	YES	17:40	
			24SEP2010	YES	8:10	YES	17:20	
			25SEP2010	YES	8:20	YES	17:00	
			26SEP2010	YES	8:10	YES	17:15	
			27SEP2010	YES	8:00	YES	17:20	
			28SEP2010	YES	8:20	YES	17:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	29SEP2010	YES	7:30	YES	17:00	
			30SEP2010	YES	8:10	YES	17:20	
			01OCT2010	YES	8:30	YES	17:10	
			02OCT2010	YES	8:15	YES	17:00	
			03OCT2010	YES	8:20	YES	17:15	
			04OCT2010	YES	8:30	YES	17:00	
			05OCT2010	YES	8:20	YES	18:00	
			06OCT2010	YES	8:10	YES	17:00	
			07OCT2010	YES	8:10	YES	17:00	
			08OCT2010	YES	8:30	YES	17:10	
			09OCT2010	YES	8:20	YES	17:20	
			10OCT2010	YES	8:10	YES	17:00	
			11OCT2010	YES	8:20	YES	17:10	
			12OCT2010	YES	8:30	YES	17:00	
			13OCT2010	YES	8:00	YES	17:10	
			13OCT2010	YES	8:10	YES	17:30	
			14OCT2010	YES	8:25	YES	17:00	
			15OCT2010	YES	8:30	YES	17:15	
			16OCT2010	YES	8:20	YES	17:30	
			17OCT2010	YES	8:30	YES	17:15	
			18OCT2010	YES	8:20	YES	17:00	
			19OCT2010	YES	8:30	YES	17:00	
			20OCT2010	YES	8:20	YES	17:10	
			21OCT2010	YES	8:10	YES	17:30	
			22OCT2010	YES	8:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	23OCT2010	YES	8:30	YES	17:10	
			24OCT2010	YES	8:20		17:30	
			25OCT2010	YES	8:20	YES	17:10	
			26OCT2010	YES	8:30	YES	17:25	
			27OCT2010	YES	8:20	YES	17:00	
			28OCT2010	YES	8:10	YES	17:00	
			29OCT2010	YES	8:30	YES	18:00	
			30OCT2010	YES	8:20	YES	17:15	
			31OCT2010	YES	8:10	YES	17:30	W2. Pat. u. Ehemann wissen bei V6 Visite am 27/12/10 nicht mehr, was W2 bedeuten soll u. warum es Ehemann notiert hat.
			01NOV2010	YES	8:25	YES	17:00	
			02NOV2010	YES	8:10	YES	17:10	
			03NOV2010	YES	8:30	YES	18:00	
			04NOV2010	YES	8:20	YES	17:00	
			05NOV2010	YES	8:10	YES	17:10	
			07NOV2010	YES	8:20	YES	17:15	
			08NOV2010	YES	8:30	YES	17:20	
			09NOV2010	YES	8:20	YES	17:15	
			10NOV2010	YES	8:20	YES	17:00	
			11NOV2010	YES	8:10	YES	18:10	
			12NOV2010	YES	8:20	YES	17:15	
			14NOV2010	YES	8:20	YES	17:00	
			15NOV2010	YES	8:30	YES	18:00	
			16NOV2010	YES	8:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	011	1	17NOV2010	YES	8:20	YES	17:00	
			18NOV2010	YES	8:00	YES	17:20	
			19NOV2010	YES	8:30	YES	17:10	
			20NOV2010	YES	8:00	YES	17:00	
			21NOV2010	YES	8:20	YES	17:10	
			22NOV2010	YES	8:30	YES	17:00	
			23NOV2010	YES	8:20	YES	17:05	
			24NOV2010	YES	8:30	YES	17:00	
			25NOV2010	YES	7:00	YES	17:00	
			26NOV2010	YES	7:30			
	013	4	16SEP2009	YES	11:30	YES	19:00	
			17SEP2009	YES	9:00	NO		
			18SEP2009	YES	8:30	YES	18:30	
			19SEP2009	YES	9:00	YES	18:10	
			20SEP2009	YES	9:30	YES	20:00	
			21SEP2009	YES	9:30	YES	20:00	
			22SEP2009	YES	10:00	YES	18:20	
			23SEP2009	YES	9:30	YES	19:00	
			24SEP2009	YES	9:30	YES	19:00	
			25SEP2009	YES	8:45	YES	23:00	
			26SEP2009	YES	7:30	YES	14:00	
			27SEP2009	YES	9:00	YES	22:30	
			28SEP2009	YES	9:30	YES	20:00	
			29SEP2009	YES	10:00	YES	23:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	30SEP2009	YES	9:30	YES	17:00	
			01OCT2009	YES	9:00	YES	18:30	
			02OCT2009	YES	9:30			
			03OCT2009	YES	9:30	YES	23:00	
			04OCT2009	YES	9:00	YES	18:00	
			05OCT2009	YES	9:30	YES	19:00	
			06OCT2009	YES	9:30	YES	18:30	
			07OCT2009	YES	9:30	YES	19:15	
			08OCT2009	YES	10:30	YES	17:00	
			09OCT2009	YES	9:00	YES	22:00	
			10OCT2009	YES	9:30	YES	20:00	
			11OCT2009	YES	9:30	YES	19:30	
			12OCT2009	YES	9:30	YES	23:30	
			13OCT2009	YES	9:00	YES	19:30	
			14OCT2009	YES	9:00			
			15OCT2009	YES	9:30	NO		
			16OCT2009	YES	9:00			
			17OCT2009	YES	9:30	YES		
			18OCT2009	YES	10:00	YES	18:30	
			19OCT2009	YES	9:30	YES	19:00	
			20OCT2009	YES	9:30	NO		
			21OCT2009	YES	9:30	YES	18:30	
			22OCT2009	YES	9:30	NO		
			23OCT2009	YES	9:30	YES	19:00	
			24OCT2009	YES	9:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	25OCT2009	YES	9:30	YES	18:00	
			26OCT2009	YES	9:30	YES	19:00	
			27OCT2009	YES	9:30	YES	18:00	
			28OCT2009	YES	9:30	YES	20:00	
			29OCT2009	YES	9:30	YES	19:00	
			30OCT2009	YES	9:30			
			31OCT2009	YES	8:30	YES	18:00	
			01NOV2009	YES	9:00	YES	18:00	
			02NOV2009	YES	9:00	YES	19:30	
			03NOV2009	YES	9:00	YES	18:00	
			04NOV2009	YES	9:30	YES	19:00	
			05NOV2009	YES	9:30	YES	21:00	
			06NOV2009	YES	9:00	YES	21:00	
			07NOV2009	YES	9:00	YES	19:00	
			08NOV2009	YES	9:00	YES	20:00	
			09NOV2009	YES	8:30	YES	18:00	
			10NOV2009	YES	8:30	YES	19:00	
			12NOV2009	YES	8:30	YES	18:00	
			13NOV2009	YES	8:30	YES	21:00	
			14NOV2009	YES	9:00	YES	19:00	
			15NOV2009	YES	9:00	YES	18:00	
			16NOV2009	YES	9:00	YES	19:00	
			17NOV2009	YES	9:00	YES	10:00	am 18.11.
			18NOV2009	YES	9:00	YES	18:00	
			19NOV2009	YES	9:00	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	20NOV2009	YES	9:00	YES	18:30	
			21NOV2009	YES	10:30	YES	18:00	
			22NOV2009	YES	9:00	YES	21:00	
			23NOV2009	YES	9:00	YES	17:30	
			24NOV2009	YES	10:30	YES	18:00	
			25NOV2009	YES	10:00	NO		
			26NOV2009	YES	9:00	YES	19:00	
			27NOV2009	YES	10:00	YES	17:00	
			28NOV2009	YES	10:00	YES	17:30	
			29NOV2009	YES	9:30	YES	18:00	
			30NOV2009	YES	9:00	YES	19:00	
			01DEC2009	YES	9:00	YES	18:00	
			02DEC2009	YES	9:00	YES	19:30	
			03DEC2009	YES	9:00	YES	20:00	
			04DEC2009	YES	9:00	YES	22:00	
			05DEC2009	YES	9:00	YES	19:00	
			06DEC2009	YES	9:00	YES	20:00	
			07DEC2009	YES	9:30	YES	18:30	
			08DEC2009	YES	9:00	YES	19:00	
			09DEC2009	YES	8:15	YES		Tablette für heute abend reserviert!
			10DEC2009	YES	9:30	YES	19:00	
			11DEC2009	YES	9:00	YES	20:00	
			12DEC2009	YES	9:00	YES	18:30	
			13DEC2009		9:30	YES	19:00	
			14DEC2009	YES	9:00	YES	21:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	15DEC2009	YES	9:00	YES	18:00	
			16DEC2009	YES	8:30	YES	22:00	
			17DEC2009	YES	9:00	YES	16:00	
			18DEC2009	YES	9:30	YES	19:00	
			19DEC2009	YES	9:00	YES	18:00	
			20DEC2009	YES	9:00	YES	22:00	
			21DEC2009	YES	9:30	YES	18:00	
			22DEC2009	YES	9:00	YES	20:00	
			23DEC2009	YES	10:00	YES	16:00	
			24DEC2009	YES	9:00	YES	18:00	
			25DEC2009	YES	9:00	YES	20:00	
			26DEC2009	YES	8:30	YES	20:00	
			27DEC2009	YES	9:30	YES	22:00	
			28DEC2009	YES	9:00	YES	15:00	
			29DEC2009	YES	9:30	YES	18:00	
			30DEC2009	YES	9:30	YES	19:00	
			31DEC2009	YES	10:00	YES	21:00	
			01JAN2010	YES	11:00	YES	16:00	
			02JAN2010	YES	10:00	YES	18:00	
			03JAN2010	YES	10:30	YES	20:00	
			04JAN2010	YES	9:30	YES	18:00	
			05JAN2010	YES	9:30	YES	20:00	
			06JAN2010	YES	9:00	YES	19:00	
			07JAN2010	YES	9:30	YES	18:00	
			08JAN2010	YES	9:30	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	09JAN2010	YES	10:00	YES	20:00	
			10JAN2010	YES	10:00	YES	21:00	
			11JAN2010	YES	8:30	YES	18:00	
			12JAN2010	YES	9:30	YES	16:00	
			13JAN2010	YES	9:30	YES	12:00	
			14JAN2010	YES	9:00	YES	20:00	
			15JAN2010	YES	9:30	YES	23:00	
			16JAN2010	YES	8:30	YES	20:00	
			17JAN2010	YES	9:00	YES	23:00	
			18JAN2010	YES	8:00	YES	13:00	
			19JAN2010	YES	9:00	YES	20:00	
			20JAN2010	YES	8:30	YES	19:00	
			21JAN2010	YES	9:30	YES	16:00	
			22JAN2010	YES	9:00	YES	20:00	
			23JAN2010	YES	8:30	YES	22:00	
			24JAN2010	YES	10:00	YES	20:00	
			25JAN2010	YES	8:00	YES	19:00	
			26JAN2010	YES	9:00	YES	18:00	
			27JAN2010	YES	9:00	YES	20:00	
			28JAN2010	YES	8:30	YES	12:00	
			29JAN2010	YES	9:00	YES	20:00	
			30JAN2010	YES	9:00	YES	16:00	
			31JAN2010	YES	9:30	YES	22:00	
			01FEB2010	YES	9:30	YES	19:00	
			02FEB2010	YES	9:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	03FEB2010	YES	9:30	YES	21:00	
			04FEB2010	YES	9:30	YES	18:00	
			05FEB2010	YES	9:30	YES	18:00	
			06FEB2010	YES	9:30	YES	22:00	
			07FEB2010	YES	9:30	YES	20:00	
			08FEB2010	YES	9:30	YES	23:00	
			09FEB2010	YES	9:00	YES	18:00	
			10FEB2010	YES	8:30	YES	20:00	
			11FEB2010	YES	9:00	YES	20:00	
			12FEB2010	YES	9:00	YES	22:00	
			13FEB2010	YES	9:30	YES	19:00	
			14FEB2010	YES	9:30	YES	18:00	
			15FEB2010	YES	9:00	YES	22:00	
			16FEB2010	YES	10:00	YES	15:00	
			17FEB2010	YES	9:30	YES	19:00	
			18FEB2010	YES	10:00	YES	20:00	
			19FEB2010	YES	9:00	YES	18:00	
			20FEB2010	YES	9:00	YES	19:00	
			21FEB2010	YES	9:30	YES	15:00	
			22FEB2010	YES	9:30	YES	20:00	
			23FEB2010	YES	9:00	YES	12:00	
			24FEB2010	YES	10:00	YES	18:00	
			25FEB2010	YES	9:30	YES	18:00	
			26FEB2010	YES	9:30	YES	21:00	
			27FEB2010	YES	10:00	YES	22:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	28FEB2010	YES	10:00	YES	22:00	
			01MAR2010	YES	9:00	YES	19:00	
			02MAR2010	YES	9:30	YES	18:00	
			03MAR2010	YES	9:30	YES	21:00	
			04MAR2010	YES	8:30			
			04MAR2010			YES	20:00	
			05MAR2010	YES	9:30	YES	18:00	
			06MAR2010	YES	9:30	YES	22:00	
			07MAR2010	YES	9:00	YES	20:00	
			08MAR2010	YES	9:00	YES	18:00	
			09MAR2010	YES	9:30	YES	21:00	
			10MAR2010	YES	8:30	YES	22:00	
			11MAR2010	YES	9:30	YES	19:00	
			12MAR2010	YES	9:30	YES	20:00	
			13MAR2010	YES	9:30	YES	21:00	
			14MAR2010	YES	10:00	YES	20:00	
			15MAR2010	YES	9:30	YES	16:00	
			16MAR2010	YES	10:00	YES	18:00	
			17MAR2010	YES	9:30	YES	22:00	
			18MAR2010	YES	9:00	YES	20:00	
			19MAR2010	YES	9:00	YES	22:00	
			20MAR2010	YES	9:00	YES	20:00	
			21MAR2010	YES	10:00	YES	18:00	
			22MAR2010	YES	9:00	YES	18:00	
			23MAR2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	24MAR2010	YES	10:00	YES	20:00	
			25MAR2010	YES	10:30	YES	21:00	
			26MAR2010	YES	9:30	YES	19:00	
			27MAR2010	YES	9:30	YES	23:00	
			28MAR2010	YES	9:30	YES	23:00	
			29MAR2010	YES	8:00	YES	18:00	
			30MAR2010	YES	7:00	YES	20:00	
			31MAR2010	YES	9:00	YES	19:30	
			01APR2010	YES	10:00	YES	20:00	
			02APR2010	YES	10:00	YES	18:00	
			03APR2010	YES	9:30	YES	19:00	
			04APR2010	YES	10:00	YES	19:00	
			05APR2010	YES	9:00	YES	19:00	
			06APR2010	YES	9:00	YES	21:00	
			07APR2010	YES	9:00	YES	23:00	
			08APR2010	YES	9:00	YES	19:00	
			09APR2010	YES	9:00	YES	18:00	
			10APR2010	YES	10:00	YES	21:00	
			11APR2010	YES	10:00	YES	19:00	
			12APR2010	YES	9:00	YES	20:00	
			13APR2010	YES	9:30	YES	23:00	
			14APR2010	YES	9:30	YES	23:00	
			15APR2010	YES	10:00	YES	20:00	
			16APR2010	YES	9:30	YES	22:00	
			17APR2010	YES	9:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	18APR2010	YES	9:00	YES	20:00	
			19APR2010	YES	9:30	YES	18:00	
			20APR2010	YES	9:00	YES	22:00	
			21APR2010	YES	9:30	YES	22:00	
			22APR2010	YES	10:00	YES	23:00	
			23APR2010	YES	9:00	YES	19:00	
			24APR2010	YES	8:00	YES	20:00	
			25APR2010	YES	9:30	YES	22:00	
			26APR2010	YES	10:00	YES	18:00	
			27APR2010	YES	10:00	YES	18:00	
			28APR2010	YES	10:00	YES	19:00	
			29APR2010	YES	10:00	YES	20:00	
			30APR2010	YES	10:00	YES	20:00	
			01MAY2010	YES	9:30	YES	21:00	
			02MAY2010	YES	9:00	YES	22:00	
			03MAY2010	YES	10:00	YES	20:00	
			04MAY2010	YES	10:00	YES	19:00	
			05MAY2010	YES	10:00	YES	19:00	
			06MAY2010	YES	10:00	YES	21:00	
			07MAY2010	YES	10:00	YES	21:00	
			08MAY2010	YES	10:00	YES	22:00	
			09MAY2010	YES	11:00	YES	20:00	
			10MAY2010	YES	10:00	YES	19:00	
			11MAY2010	YES	9:30	YES	19:00	
			12MAY2010	YES	8:30	YES	22:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	13MAY2010	YES	10:00	YES	18:00	
			14MAY2010	YES	9:30	YES	20:00	
			15MAY2010	YES	9:30	YES	19:00	
			16MAY2010	YES	9:30	YES	20:00	
			17MAY2010	YES	10:00	YES	22:00	
			18MAY2010	YES	10:00	YES	23:00	
			19MAY2010	YES	9:30	YES	20:00	
			20MAY2010	YES	8:30			
			20MAY2010			YES	20:00	
			21MAY2010	YES	9:00	YES	19:00	
			22MAY2010	YES	10:00	YES	20:00	
			23MAY2010	YES	10:00	YES	21:00	
			24MAY2010	YES	10:30	YES	20:00	
			25MAY2010	YES	10:30	YES	23:00	
			26MAY2010	YES	10:00	YES	21:00	
			27MAY2010	YES	10:00	YES	18:00	
			28MAY2010	YES		YES	23:00	
			29MAY2010	YES	10:00	YES	19:00	
			30MAY2010	YES	9:00	YES	20:00	
			31MAY2010	YES	10:00	YES	22:00	
			01JUN2010		9:30	YES	22:00	
			02JUN2010	YES	9:00	YES	20:00	
			03JUN2010	YES	10:00	YES	18:00	
			04JUN2010	YES	10:00	YES	22:00	
			05JUN2010	YES	10:00	YES	21:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	06JUN2010	YES	9:30	YES	22:00	
			07JUN2010	YES	9:00	YES	20:00	
			08JUN2010	YES	10:00	YES	18:00	
			09JUN2010	YES	9:30	YES	15:00	
			10JUN2010	YES	10:00	YES	20:00	
			11JUN2010	YES	10:00	YES	22:00	
			12JUN2010	YES	10:00	YES	22:00	
			13JUN2010	YES	9:00	YES	23:00	
			14JUN2010	YES	9:30	YES	20:00	
			15JUN2010	YES	9:30	YES	23:00	
			16JUN2010	YES	9:00	YES	20:00	
			17JUN2010	YES	9:30	YES	18:00	
			18JUN2010	YES	10:00	YES	22:00	
			19JUN2010	YES	10:00	YES	23:00	
			20JUN2010	YES	10:00	YES	19:00	
			21JUN2010	YES	9:30	YES	18:00	
			22JUN2010	YES	8:30	YES	20:00	
			23JUN2010	YES	9:00	YES	18:00	
			24JUN2010	YES	10:00	YES	23:00	
			25JUN2010	YES	9:00	YES	22:00	
			26JUN2010	YES	9:00	YES	20:00	
			27JUN2010	YES	10:00	YES	23:00	
			28JUN2010	YES	10:00	YES	18:00	
			29JUN2010	YES	9:00	YES	20:00	
			30JUN2010	YES	10:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	01JUL2010	YES	9:00	YES	20:00	
			02JUL2010	YES	9:30	YES	19:00	
			03JUL2010	YES	9:30	YES	22:00	
			04JUL2010	YES	9:30	YES	18:00	
			05JUL2010	YES	9:00	YES	20:00	
			06JUL2010	YES	9:30	YES	21:00	
			07JUL2010	YES	9:30	YES	21:00	
			08JUL2010	YES	9:00	YES	19:00	
			09JUL2010	YES	9:30	YES	21:00	
			10JUL2010	YES	9:30	YES	23:00	
			11JUL2010	YES	10:00	YES	18:00	
			12JUL2010	YES	10:00	YES	17:00	
			13JUL2010	YES	8:30	YES	20:00	
			14JUL2010	YES	8:30	YES	19:00	
			15JUL2010	YES	8:30	YES	22:00	
			16JUL2010	YES	9:00	YES	23:00	
			17JUL2010	YES	9:00	YES	19:00	
			18JUL2010	YES	8:30	YES	19:00	
			19JUL2010	YES	8:30	YES	20:00	
			20JUL2010	YES	8:30	YES	20:00	
			21JUL2010	YES	8:30	YES	22:00	
			22JUL2010	YES	8:30	YES	16:00	
			23JUL2010	YES	9:30	YES	20:00	
			24JUL2010	YES	9:30	YES	19:00	
			25JUL2010	YES	9:30	YES	21:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	26JUL2010	YES	10:00	YES	22:00	
			27JUL2010	YES	10:30	YES	19:00	
			28JUL2010	YES	9:30	YES	21:00	
			29JUL2010	YES	9:30	YES	18:00	
			30JUL2010	YES	9:00	YES	19:00	
			31JUL2010	YES	9:00	YES	20:00	
			01AUG2010	YES	9:00	YES	22:00	
			02AUG2010	YES	9:00	YES	18:00	
			03AUG2010	YES	9:30	YES	20:00	
			04AUG2010	YES	9:00	YES	22:00	
			05AUG2010	YES	9:00	YES	19:00	
			06AUG2010	YES	9:00	YES	19:00	
			07AUG2010	YES	9:00	YES	19:00	
			08AUG2010	YES	9:30	YES	22:00	
			09AUG2010	YES	9:00	YES	20:00	
			10AUG2010	YES	10:00	YES	22:00	
			11AUG2010	YES	9:30	YES	19:00	
			12AUG2010	YES	9:00	YES	20:00	
			13AUG2010	YES	9:30	YES	21:00	
			14AUG2010	YES	9:30	YES	18:00	
			15AUG2010	YES	10:30	YES	19:00	
			16AUG2010	YES	11:00	YES	19:00	
			17AUG2010	YES	10:00	YES	20:00	
			18AUG2010	YES	9:00	YES	19:00	
			19AUG2010	YES	8:30	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	20AUG2010	YES	9:30	YES	22:00	
			21AUG2010	YES	10:00	YES	18:00	
			22AUG2010	YES	12:00	YES	20:00	
			23AUG2010	YES	11:00	YES	23:00	
			24AUG2010	YES	9:00	YES	19:30	
			25AUG2010	YES	9:30	YES	20:00	
			26AUG2010	YES	9:00	YES	22:00	
			27AUG2010	YES	10:00	YES	20:00	
			28AUG2010	YES	9:30	YES	19:00	
			29AUG2010	YES	9:00	YES	20:00	
			30AUG2010	YES	10:00	YES	18:00	
			31AUG2010	YES	9:30	YES	19:00	
			01SEP2010	YES	9:00	YES	20:00	
			02SEP2010	YES	9:30	YES	21:00	
			03SEP2010	YES	9:30	YES		
			04SEP2010	YES	9:30	YES	20:00	
			05SEP2010	YES	9:30	YES	19:00	
			06SEP2010	YES	9:30	YES	20:00	
			07SEP2010	YES	9:30	YES	22:00	
			08SEP2010	YES	9:30	YES	23:00	
			09SEP2010	YES	9:30	YES	21:00	
			10SEP2010	YES	9:30	YES	20:00	
			11SEP2010	YES	10:00	YES	23:00	
			12SEP2010	YES	10:00	YES	19:00	
			13SEP2010	YES	9:00	YES	23:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	013	4	14SEP2010	YES	9:00	YES	20:00	
			15SEP2010	YES	9:00	YES	21:00	
			16SEP2010	YES	8:00			
	016	4	01MAR2010			YES	18:15	
			02MAR2010	YES	7:15	YES	18:30	
			03MAR2010	YES	7:45	YES	18:45	
			04MAR2010	YES	6:45	YES	18:30	
			05MAR2010	YES	7:40	YES	19:00	
			06MAR2010	YES	9:10	YES	19:10	
			07MAR2010	YES	9:45	YES	19:15	
			08MAR2010	YES	7:45	YES	18:10	
			09MAR2010	YES	7:30	YES	19:00	
			10MAR2010	YES	7:30	YES	19:00	
			11MAR2010	YES	6:45	YES	18:25	
			12MAR2010	YES	7:30	YES	18:15	
			13MAR2010	YES	9:05	YES	18:25	
			14MAR2010	YES	9:45		18:45	
			15MAR2010	YES	7:45	YES	18:15	
			16MAR2010		8:00	YES	18:05	
			17MAR2010	YES	8:00	YES	18:10	
			18MAR2010	YES	6:45	YES	18:20	
			19MAR2010	YES	7:45	YES	18:25	
			20MAR2010	YES	9:10	YES	18:45	
			21MAR2010	YES	9:15		19:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	22MAR2010	YES	7:25	YES	18:05	
			23MAR2010	YES	8:05	YES	19:00	
			24MAR2010	YES	7:55	YES	18:20	
			25MAR2010	YES	6:40	YES	18:20	
			26MAR2010	YES	7:30	YES	18:50	
			27MAR2010	YES	9:25	YES	19:05	
			28MAR2010	YES	9:20	YES	19:10	
			29MAR2010	YES	7:40			
			29MAR2010			YES	19:15	
			30MAR2010	YES	8:10	YES	19:30	
			31MAR2010	YES	6:30	YES	19:30	
			01APR2010	YES	7:45	YES	19:25	
			02APR2010	YES	9:45	YES	18:45	
			03APR2010	YES	8:45	YES	19:10	
			04APR2010	YES	8:30	YES	19:15	
			05APR2010	YES	9:10		19:20	
			06APR2010	YES	8:15	YES	19:30	
			07APR2010	YES	9:20	YES	19:10	
			08APR2010	YES	7:15	YES	18:50	
			09APR2010	YES	7:45	YES	18:20	
			10APR2010	YES	9:45	YES	19:00	
			11APR2010	YES	9:25	YES	18:50	
			12APR2010	YES	7:50	YES	18:30	
			13APR2010	YES	8:05	YES	19:30	
			14APR2010	YES	6:50	YES	18:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	15APR2010	YES	7:50	YES	18:40	
			16APR2010	YES	7:20	YES	18:15	vormittags schwindlig, Sehprobleme
			17APR2010	YES	9:10	YES	18:55	
			18APR2010	YES	8:50	YES	19:20	vormittags schwindlig, Sehprobleme
			19APR2010	YES	8:00	YES	19:05	vormittags schwindlig, Sehprobleme
			20APR2010		7:55		19:30	vormittags schwindlig, Sehprobleme
			21APR2010	YES	6:45	YES	18:30	vormittags schwindlig, Sehprobleme
			22APR2010	YES	7:35	YES	18:50	vormittags schwindlig, Sehprobleme
			23APR2010	YES	7:30	YES	18:20	
			24APR2010	YES	9:30	YES	19:30	
			25APR2010	YES	9:10	YES	19:00	
			26APR2010	YES	7:55	YES	18:20	
			27APR2010	YES	7:35	YES	18:30	
			28APR2010	YES	7:40	YES	18:35	
			29APR2010	YES	8:10	YES	18:40	
			30APR2010	YES	7:50	YES	19:05	
			01MAY2010	YES	9:10	YES	19:10	
			02MAY2010	YES	9:20	YES	18:50	
			03MAY2010	YES	7:40	YES	18:35	
			04MAY2010	YES	7:40	YES	18:35	
			05MAY2010	YES	6:40	YES	18:50	
			06MAY2010	YES	7:35	YES	19:35	
			07MAY2010	YES	7:40	YES	19:05	
			08MAY2010	YES	9:10	YES	19:50	
			09MAY2010	YES	9:15	YES	19:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	10MAY2010	YES	7:45	YES	18:25	
			11MAY2010	YES	7:40	YES	18:30	
			12MAY2010	YES	6:40	YES	18:45	
			13MAY2010	YES	8:35	YES	19:10	
			14MAY2010	YES	7:50	YES	19:20	
			15MAY2010	YES	9:25	YES	19:10	
			16MAY2010	YES	8:50	YES	19:20	
			17MAY2010	YES	7:50	YES	18:40	
			18MAY2010	YES	7:40	YES	18:50	
			19MAY2010	YES	7:25			
			19MAY2010	YES		YES	18:40	morgens: alte Pckg.
			20MAY2010	YES	6:50	YES	18:50	Schwindel
			21MAY2010	YES	7:30	YES	19:55	
			22MAY2010	YES	8:55	YES	19:50	
			23MAY2010	YES	10:05	YES	19:20	
			24MAY2010	YES	7:40	YES	19:10	
			25MAY2010	YES	8:10	YES	18:50	
			26MAY2010	YES	7:05	YES	18:40	
			27MAY2010	YES	7:35	YES	18:55	
			28MAY2010	YES	8:10	YES	18:45	
			29MAY2010	YES	9:15	YES	19:10	
			30MAY2010	YES	9:40	YES	19:20	
			31MAY2010	YES	7:45	YES	18:25	
			01JUN2010	YES	7:50	YES	18:40	
			02JUN2010	YES	7:05	YES	18:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	03JUN2010	YES	8:20	YES	19:10	
			04JUN2010	YES	7:40	YES	19:10	
			05JUN2010	YES	9:20	YES	19:25	
			06JUN2010	YES	9:25	YES	19:10	
			07JUN2010	YES	7:35	YES	18:30	
			08JUN2010	YES	7:25	YES	18:40	
			09JUN2010	YES	7:05	YES	19:00	
			10JUN2010	YES	8:40	YES	18:30	
			11JUN2010	YES	7:50	YES	19:05	
			12JUN2010	YES	9:10	YES	19:25	
			13JUN2010	YES	9:25	YES	19:20	
			14JUN2010	YES	7:40	YES	18:20	
			15JUN2010	YES	7:35	YES	18:10	
			16JUN2010	YES	7:45	YES	18:20	
			17JUN2010	YES	6:50	YES	18:25	
			18JUN2010	YES	7:40	YES	18:35	
			19JUN2010	YES	9:20	YES	20:05	
			20JUN2010	YES	9:50	YES	19:45	
			21JUN2010	YES	8:05	YES	18:50	
			22JUN2010	YES	7:50	YES	18:20	
			23JUN2010	YES	7:45	YES	18:25	
			24JUN2010	YES	6:45	YES	18:25	
			25JUN2010	YES	7:35	YES	18:50	
			26JUN2010	YES	7:40	YES	19:40	
			27JUN2010	YES	9:40	YES	19:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	28JUN2010	YES	7:25	YES	18:50	
			29JUN2010	YES	7:50	YES	18:40	
			30JUN2010	YES	7:35	YES	7:20	
			01JUL2010	YES	6:40	YES	19:25	
			02JUL2010	YES	7:25	YES	19:10	
			03JUL2010	YES	9:20	YES	19:20	
			04JUL2010	YES	9:35	YES	19:50	
			05JUL2010	YES	7:50	YES	18:25	
			06JUL2010	YES	7:35	YES	18:20	
			07JUL2010	YES	6:50	YES	18:40	
			08JUL2010	YES	7:40	YES	18:40	
			09JUL2010	YES	7:50	YES	19:10	
			10JUL2010	YES	8:40	YES	19:05	
			11JUL2010	YES	9:25	YES	19:10	
			12JUL2010	YES	7:35	YES	18:20	
			13JUL2010	YES	6:55	YES	18:30	
			14JUL2010	YES	7:40	YES	18:30	
			15JUL2010	YES	7:35	YES	18:40	
			16JUL2010	YES	7:40	YES	19:15	
			17JUL2010	YES	9:10	YES	19:20	
			18JUL2010	YES	9:35	YES	19:10	
			19JUL2010	YES	7:30	YES	18:25	
			20JUL2010	YES	7:25	YES	18:10	
			21JUL2010	YES	6:55	YES	18:25	
			22JUL2010	YES	7:40	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	23JUL2010	YES	7:55	YES	18:50	
			24JUL2010	YES	9:10	YES	19:15	
			25JUL2010	YES	9:30	YES	19:20	
			26JUL2010	YES	7:50	YES		
			27JUL2010	YES	7:05	YES	18:30	
			28JUL2010	YES	7:35	YES	18:45	
			29JUL2010	YES	7:40	YES	18:50	
			30JUL2010	YES	7:40	YES	19:20	
			31JUL2010	YES	8:55	YES	19:35	
			01AUG2010	YES	9:20	YES	19:10	
			02AUG2010	YES	8:10	YES	18:50	
			03AUG2010	YES	7:55	YES	18:50	
			04AUG2010	YES	7:50	YES	18:55	
			05AUG2010	YES	8:05	YES	18:40	
			06AUG2010	YES	7:55	YES	19:15	
			07AUG2010	YES	9:05	YES	19:40	
			08AUG2010	YES	8:50	YES	19:10	
			09AUG2010	YES	7:40			
			09AUG2010			YES	19:20	
			10AUG2010	YES	7:35	YES	18:10	
			11AUG2010	YES	7:50	YES	18:40	
			12AUG2010	YES	6:55	YES	18:20	
			13AUG2010	YES	8:10	YES	19:05	
			14AUG2010	YES	9:20	YES	19:35	
			15AUG2010	YES	9:35	YES	19:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	16AUG2010	YES	7:50	YES	18:40	
			17AUG2010	YES	7:55	YES	18:30	
			18AUG2010	YES	7:10	YES	18:45	
			19AUG2010	YES	7:50	YES	19:10	
			20AUG2010	YES	8:10	YES	19:05	
			21AUG2010	YES	9:25	YES	19:40	
			22AUG2010	YES	9:45	YES	19:05	
			23AUG2010	YES	8:15	YES	18:30	
			24AUG2010	YES	7:50	YES	18:40	
			25AUG2010	YES	7:05	YES	18:30	
			26AUG2010	YES	7:40	YES	18:25	
			27AUG2010	YES	8:10	YES	19:10	
			28AUG2010	YES	9:25	YES	19:35	
			29AUG2010	YES	9:40	YES	19:05	
			30AUG2010	YES	7:55	YES	18:20	
			31AUG2010	YES	7:25	YES	18:40	
			01SEP2010	YES	7:40	YES	18:30	
			02SEP2010	YES	6:55	YES	18:20	
			03SEP2010	YES	7:50	YES	19:15	
			04SEP2010	YES	9:30	YES	19:40	
			05SEP2010	YES	9:25	YES	19:20	
			06SEP2010	YES	7:40	YES	18:15	
			07SEP2010	YES	7:50	YES	18:30	
			08SEP2010	YES	7:30	YES	18:20	
			09SEP2010	YES	6:50	YES	18:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	10SEP2010	YES	7:50	YES	19:10	
			11SEP2010	YES	9:25	YES	19:25	
			12SEP2010	YES	9:40	YES	19:10	
			13SEP2010	YES	7:35	YES	18:20	
			14SEP2010	YES	6:55	YES	18:15	
			15SEP2010	YES	7:35	YES	18:25	
			16SEP2010	YES	7:40	YES	18:10	
			17SEP2010	YES	7:35	YES	19:05	
			18SEP2010	YES	9:20	YES	19:20	
			19SEP2010	YES	9:40	YES	19:05	
			20SEP2010	YES	7:30	YES	18:20	
			21SEP2010	YES	7:45	YES	18:30	
			22SEP2010	YES	6:50	YES	18:30	
			23SEP2010	YES	7:40	YES	18:40	
			24SEP2010	YES	7:35	YES	19:05	
			25SEP2010	YES	9:25	YES	19:35	
			26SEP2010	YES	9:35	YES	19:10	
			27SEP2010	YES	7:30	YES	18:20	
			28SEP2010	YES	7:25	YES	18:10	
			29SEP2010	YES	7:30	YES	18:40	
			30SEP2010	YES	6:50	YES	18:25	
			01OCT2010	YES	7:50	YES	19:10	
			02OCT2010	YES	9:25	YES	19:20	
			03OCT2010	YES	9:15	YES	19:05	
			04OCT2010	YES	7:25	YES	18:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	05OCT2010	YES	7:30	YES	18:20	
			06OCT2010	YES	7:40	YES	18:40	
			07OCT2010	YES	6:45	YES	18:10	
			08OCT2010	YES	7:45	YES	19:05	
			09OCT2010	YES	9:35	YES	19:45	
			10OCT2010	YES	9:40	YES	19:05	
			11OCT2010	YES	7:25	YES	18:10	
			12OCT2010	YES	7:50	YES	18:25	
			13OCT2010	YES	7:40	YES	18:45	
			14OCT2010	YES	6:50	YES	18:05	
			15OCT2010	YES	7:40	YES	19:20	
			16OCT2010	YES	9:25	YES	19:40	
			17OCT2010	YES	9:50	YES	19:05	
			18OCT2010	YES	7:40	YES	18:25	
			19OCT2010	YES	7:15	YES	18:50	
			20OCT2010	YES	7:45	YES	18:50	
			21OCT2010	YES	6:55	YES	18:10	
			22OCT2010	YES	7:50	YES	19:15	
			23OCT2010	YES	9:15	YES	19:40	
			24OCT2010	YES	9:40	YES	19:10	
			25OCT2010	YES	7:55	YES	18:05	
			26OCT2010	YES	7:50	YES	18:10	
			27OCT2010	YES	7:50	YES	18:45	
			28OCT2010	YES	6:45	YES	18:15	
			29OCT2010	YES	7:50	YES	19:20	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	30OCT2010	YES	9:25	YES	19:40	
			31OCT2010	YES	9:50	YES	19:25	
			01NOV2010	YES	7:40	YES	18:20	
			02NOV2010	YES	7:35	YES	18:15	
			03NOV2010	YES	6:55	YES	18:25	
			04NOV2010	YES	7:35	YES	18:45	
			05NOV2010	YES	7:55	YES	19:15	
			06NOV2010	YES	9:35	YES	19:35	
			07NOV2010	YES	9:25	YES	19:15	
			08NOV2010	YES	7:30			Fehlend: 4 Tabletten
			08NOV2010			YES	18:25	
			09NOV2010	YES	7:40	YES	18:20	
			10NOV2010	YES	8:05	YES	18:45	
			11NOV2010	YES	6:50	YES	18:05	
			12NOV2010	YES	8:50	YES	18:50	
			13NOV2010	YES	9:15	YES	19:10	
			14NOV2010	YES	9:30	YES	18:55	
			15NOV2010	YES	7:35	YES	18:10	
			16NOV2010	YES	7:30	YES	18:25	
			17NOV2010	YES	7:45	YES	18:40	
			18NOV2010	YES	6:55	YES	18:05	
			19NOV2010	YES	7:45	YES	19:15	
			20NOV2010	YES	9:20	YES	19:25	
			21NOV2010	YES	9:40	YES	18:40	
			22NOV2010	YES	7:25	YES	17:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	23NOV2010	YES	7:30	YES	18:20	
			24NOV2010	YES	7:30	YES	18:10	
			25NOV2010	YES	7:10	YES	18:15	
			26NOV2010	YES	7:40	YES	18:55	
			27NOV2010	YES	9:20	YES	19:25	
			28NOV2010	YES	9:45	YES	19:10	
			29NOV2010	YES	7:25	YES	18:10	
			30NOV2010	YES	7:40	YES	18:35	
			01DEC2010	YES	7:55	YES	18:10	
			02DEC2010	YES	6:50	YES	18:20	
			03DEC2010	YES	7:55	YES	19:10	
			04DEC2010	YES	9:10	YES	19:25	
			05DEC2010	YES	9:45	YES	18:50	
			06DEC2010	YES	7:40	YES	18:10	
			07DEC2010	YES	7:45	YES	18:05	
			08DEC2010	YES	6:55	YES	18:05	
			09DEC2010	YES	7:55	YES	18:20	
			10DEC2010	YES	7:45	YES	19:05	
			11DEC2010	YES	9:25	YES	19:20	
			12DEC2010	YES	9:50	YES	18:50	
			13DEC2010	YES	7:35	YES	18:10	
			14DEC2010	YES	7:30	YES	18:10	
			15DEC2010	YES	7:40	YES	18:35	
			16DEC2010	YES	6:50	YES	18:05	
			17DEC2010	YES	7:55	YES	19:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	18DEC2010	YES	9:30	YES	19:40	
			19DEC2010	YES	9:45	YES	18:20	
			20DEC2010	YES	7:35	YES	17:55	
			21DEC2010	YES	7:40	YES	18:05	
			22DEC2010	YES	7:50	YES	18:10	
			23DEC2010	YES	6:55	YES	18:20	
			24DEC2010	YES	8:20	YES	19:45	
			25DEC2010	YES	10:05	YES	19:20	
			26DEC2010	YES	9:05	YES	19:10	
			27DEC2010	YES	8:10	YES	19:05	
			28DEC2010	YES	8:05	YES	18:55	
			29DEC2010	YES	7:55	YES	18:40	
			30DEC2010	YES	7:05	YES	18:20	
			31DEC2010	YES	8:10	YES	19:50	
			01JAN2011	YES	10:20	YES	19:25	
			02JAN2011	YES	9:55	YES	19:20	
			03JAN2011	YES	7:20	YES	18:25	
			04JAN2011	YES	7:40	YES	18:35	
			05JAN2011	YES	7:25	YES	18:10	
			06JAN2011	YES	6:55	YES	17:50	
			07JAN2011	YES	7:40	YES	19:15	
			08JAN2011	YES	9:25	YES	19:20	
			09JAN2011	YES	9:40	YES	19:05	
			10JAN2011	YES	7:25	YES	18:05	
			11JAN2011	YES	7:25	YES	18:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	12JAN2011	YES	7:40	YES	18:25	
			13JAN2011	YES	6:50	YES	18:15	
			14JAN2011	YES	7:45	YES	19:20	
			15JAN2011	YES	9:15	YES	19:40	
			16JAN2011	YES	9:40	YES	19:05	
			17JAN2011	YES	7:40	YES	18:10	
			18JAN2011	YES	7:45	YES	18:25	
			19JAN2011	YES	7:35	YES	18:30	
			20JAN2011	YES	6:55	YES	18:25	
			21JAN2011	YES	7:30	YES	19:05	
			22JAN2011	YES	9:20	YES	19:40	
			23JAN2011	YES	9:45	YES	19:10	
			24JAN2011	YES	7:25	YES	18:15	
			25JAN2011	YES	7:35	YES	18:20	
			26JAN2011	YES	7:45	YES	18:10	
			27JAN2011	YES	6:55	YES	18:05	
			28JAN2011	YES	8:15	YES	18:55	
			29JAN2011	YES	9:30	YES	19:25	
			30JAN2011	YES	9:40	YES	19:05	
			31JAN2011	YES	7:40	YES	18:05	
			01FEB2011	YES	7:55	YES	17:55	
			02FEB2011	YES	7:50	YES	18:10	
			03FEB2011	YES	7:05	YES	18:05	
			04FEB2011	YES	7:35	YES	19:05	
			05FEB2011	YES	9:30	YES	19:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	016	4	06FEB2011	YES	9:50	YES	19:10	
			07FEB2011	YES	7:45	YES	18:10	
			08FEB2011	YES	7:50	YES	18:20	
			09FEB2011	YES	7:45	YES	18:15	
			10FEB2011	YES	6:55	YES	18:05	
			11FEB2011	YES	7:40	YES	19:20	
			12FEB2011	YES	9:25	YES	19:30	
			13FEB2011	YES	9:40	YES	19:10	
			14FEB2011	YES	7:50	YES	18:05	
			15FEB2011	YES	7:55	YES	18:20	
			16FEB2011	YES	6:30	YES	18:10	
			17FEB2011	YES	8:45	YES	18:20	
			18FEB2011	YES	8:35	YES	19:10	
			19FEB2011	YES	9:30	YES	19:25	
			20FEB2011	YES	9:50	YES	19:05	
			21FEB2011	YES	8:20	YES	18:10	
			22FEB2011	YES	8:10	YES	18:20	
			23FEB2011	YES	8:05	YES	18:25	
			24FEB2011	YES	8:05	YES	18:10	
			25FEB2011	YES	8:05	YES	18:10	
			26FEB2011	YES	9:30	YES	19:50	
			27FEB2011	YES	9:45	YES	19:05	
			28FEB2011	YES	7:10			

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5						Tabletten wurden bis einschließlich 25.12. aus der ersten Medikamentenpackung entnommen, d.h. 9 Tabletten sind zusätzlich abzuziehen.
			23NOV2009			YES	19:00	
			24NOV2009	YES	7:30	YES	18:00	
			25NOV2009	YES	7:15	YES	17:45	
			26NOV2009	YES	7:30	YES	18:00	
			27NOV2009	YES	7:30	YES	18:45	
			28NOV2009	YES	8:10	YES	18:15	
			29NOV2009	YES	8:30	YES	17:45	
			30NOV2009	YES	7:45	YES	19:45	
			01DEC2009	YES	7:45	YES	19:00	
			02DEC2009	YES	7:30	YES	18:30	
			03DEC2009	YES	8:00	YES	18:15	
			04DEC2009	YES	7:30	YES	18:30	
			05DEC2009	YES	8:00	YES	18:30	
			06DEC2009	YES	9:00	YES	18:15	
			07DEC2009	YES	7:00	YES	18:00	
			08DEC2009	YES	7:45	YES	20:00	
			09DEC2009	YES	6:00		18:00	
			10DEC2009	YES	7:30	YES	17:30	
			11DEC2009	YES	8:00	YES	18:00	
			12DEC2009	YES	7:30	YES	18:00	
			13DEC2009	YES	8:30	YES	18:00	
			14DEC2009	YES	8:15	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	15DEC2009	YES	8:15	YES	18:45	
			16DEC2009	YES	8:30	YES	17:45	
			17DEC2009	YES	9:00	YES	18:00	
			18DEC2009	YES	9:00	YES	17:45	
			19DEC2009	YES	8:50	YES	18:15	
			20DEC2009	YES	9:00	YES	18:15	
			21DEC2009	YES	5:45			
			21DEC2009			YES	17:45	
			22DEC2009	YES	7:30	YES	17:50	
			23DEC2009	YES	9:00	YES	18:00	
			24DEC2009	YES	7:30	YES	18:10	
			25DEC2009	YES	8:45	YES	18:50	
			26DEC2009	YES	8:00	YES	19:00	
			27DEC2009	YES	8:30	YES	18:15	
			28DEC2009	YES	8:00	YES	18:10	
			29DEC2009	YES	9:00	YES	18:00	
			30DEC2009	YES	7:45	YES	18:30	
			31DEC2009	YES	9:15	YES	18:30	
			01JAN2010	YES	8:30	YES	18:00	
			02JAN2010	YES	8:00	YES	17:45	
			03JAN2010	YES	8:30	YES	18:30	
			04JAN2010	YES	7:30	YES	18:15	
			05JAN2010	YES	9:15	YES	18:00	
			06JAN2010	YES	7:00	YES	18:00	
			07JAN2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	08JAN2010	YES	7:15	YES	18:00	
			09JAN2010	YES	7:45	YES	18:15	
			10JAN2010	YES	9:00	YES	18:00	
			11JAN2010	YES	8:30	YES	18:00	
			12JAN2010	YES	7:00	YES	18:00	
			13JAN2010	YES	7:00	YES	18:00	
			14JAN2010	YES	6:30	YES	18:30	
			15JAN2010	YES	7:30	YES	18:30	
			16JAN2010	YES	9:00	YES	17:45	
			17JAN2010	YES	9:15	YES	18:00	
			18JAN2010	YES	9:15	YES	18:45	
			19JAN2010	YES	6:45	YES	18:10	
			20JAN2010	YES	6:30	YES	18:50	
			21JAN2010	YES	10:00	YES	18:00	
			22JAN2010	YES	6:45	YES	18:00	
			23JAN2010	YES	9:00	YES	18:30	
			24JAN2010	YES	8:00	YES	18:30	
			25JAN2010	YES	7:30	YES	18:00	
			26JAN2010	YES	6:30	YES	18:00	
			27JAN2010	YES	7:20	YES	17:45	
			28JAN2010	YES	6:30	YES	18:30	
			29JAN2010	YES	6:30	YES	17:45	
			30JAN2010	YES	7:30	YES	18:00	
			31JAN2010	YES	9:30	YES	18:30	
			01FEB2010	YES	7:30	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	02FEB2010	YES	6:40	YES	18:10	
			03FEB2010	YES	7:40	YES	18:45	
			04FEB2010	YES	7:30	YES	17:40	
			05FEB2010	YES	8:45	YES	18:00	
			06FEB2010	YES	8:00	YES	18:15	
			07FEB2010	YES	8:00	YES	18:00	
			08FEB2010	YES	7:30	YES	19:00	
			09FEB2010	YES	9:00	YES	17:50	
			10FEB2010	YES	7:00	YES	18:00	
			11FEB2010	YES	8:15	YES	17:15	
			12FEB2010	YES	8:00	YES	18:00	
			13FEB2010	YES	8:15	YES	20:00	
			14FEB2010	YES	8:00	YES	17:30	
			15FEB2010	YES	8:45	YES	18:30	
			16FEB2010	YES	6:20			
			16FEB2010			YES	18:00	
			17FEB2010	YES	6:15	YES	18:10	
			18FEB2010	YES	7:45	YES	18:00	
			19FEB2010	YES	6:30	YES	17:45	
			20FEB2010	YES	9:10	YES	17:45	
			21FEB2010	YES	8:45	YES	18:00	
			22FEB2010	YES	6:30	YES	17:45	
			23FEB2010	YES	8:30	YES	17:30	
			24FEB2010	YES	8:50	YES	18:00	
			25FEB2010	YES	8:30	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	26FEB2010	YES	6:45	YES	17:45	
			27FEB2010	YES	9:10	YES	17:45	
			28FEB2010	YES	10:30	YES	18:30	
			01MAR2010	YES	10:15	YES	18:20	
			02MAR2010	YES	7:00	YES	18:00	
			03MAR2010	YES	6:45	YES	18:00	
			04MAR2010	YES	7:10	YES	18:00	
			05MAR2010	YES	8:45	YES	18:00	
			06MAR2010	YES	9:00	YES	18:00	
			07MAR2010	YES	9:15	YES	17:30	
			08MAR2010	YES	7:15	YES	18:00	
			09MAR2010	YES	10:30	YES	19:00	
			10MAR2010	YES	8:15	YES	17:45	
			11MAR2010	YES	6:40	YES	18:00	
			12MAR2010	YES	7:45	YES	18:00	
			13MAR2010	YES	7:30	YES	17:00	
			14MAR2010	YES	7:30	YES	19:15	
			15MAR2010	YES	6:15	YES	18:00	
			16MAR2010	YES	6:45	YES	18:00	
			17MAR2010	YES	6:45	YES	17:50	
			18MAR2010	YES	6:20	YES	17:45	
			19MAR2010	YES	7:10	YES	17:45	
			20MAR2010	YES	9:00	YES	18:00	
			21MAR2010	YES	9:00	YES	18:00	
			22MAR2010	YES	7:00	YES	17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	23MAR2010	YES	8:30	YES	18:00	
			24MAR2010	YES	7:20	YES	18:00	
			25MAR2010	YES	7:45	YES	18:00	
			26MAR2010	YES	8:40	YES	18:00	
			27MAR2010	YES	10:00	YES	18:15	
			28MAR2010	YES	10:00	YES	18:00	
			29MAR2010	YES	7:00	YES	18:00	
			30MAR2010	YES	7:45	YES	17:50	
			31MAR2010	YES	7:45	YES	17:45	
			01APR2010	YES	7:45	YES	18:00	
			02APR2010	YES	9:30	YES	18:00	
			03APR2010	YES	8:00	YES	18:00	
			04APR2010	YES	8:45	YES	17:45	
			05APR2010	YES	10:40	YES	18:40	
			06APR2010	YES	8:00	YES	18:10	
			07APR2010	YES	7:30	YES	17:40	
			08APR2010	YES	7:30	YES	18:00	
			09APR2010	YES	7:00	YES	17:50	
			10APR2010	YES	8:00	YES	20:00	
			11APR2010	YES	8:00	YES	18:10	
			12APR2010	YES	7:00	YES	18:00	
			13APR2010	YES	7:15	YES	17:30	
			14APR2010	YES	7:00	YES	17:45	
			15APR2010	YES	7:00	YES	18:00	
			16APR2010	YES	7:15	YES	17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	17APR2010	YES	9:30	YES	17:45	
			18APR2010	YES	9:30	YES	18:00	
			19APR2010	YES	6:45	YES	17:30	
			20APR2010	YES	8:00	YES	18:00	
			21APR2010	YES	7:00	YES	18:00	
			22APR2010	YES	7:45	YES	18:00	
			23APR2010	YES	7:00	YES	18:00	
			24APR2010	YES	8:00	YES	18:20	
			25APR2010	YES	8:30	YES	19:15	
			26APR2010	YES	6:45	YES	18:00	
			27APR2010	YES	8:30		18:00	
			28APR2010	YES	8:30	YES	18:15	
			29APR2010	YES	8:00	YES	19:40	
			30APR2010	YES	7:00	YES	19:00	
			01MAY2010	YES	9:00	YES	17:30	
			02MAY2010	YES	9:45	YES	18:00	
			03MAY2010	YES	6:15	YES	18:10	
			04MAY2010	YES	9:30	YES	17:30	
			05MAY2010	YES	7:30	YES	17:30	
			06MAY2010	YES	8:00	YES	17:45	
			07MAY2010	YES	7:50	YES	17:30	
			08MAY2010	YES	7:15	YES	21:00	
			09MAY2010	YES	8:00	YES	18:30	
			10MAY2010	YES	5:40	YES	18:00	
			11MAY2010	YES	6:00			

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	12MAY2010			YES	18:00	
			13MAY2010	YES	7:45	YES	17:30	
			14MAY2010	YES	8:00	YES	19:30	
			15MAY2010	YES	9:45	YES	18:30	
			16MAY2010	YES	7:00	YES	18:15	
			17MAY2010	YES	7:00	YES	18:00	
			18MAY2010	YES	7:30	YES	19:00	
			19MAY2010	YES	7:30	YES	18:15	
			20MAY2010	YES	7:30	YES	18:00	
			21MAY2010	YES	6:00	YES	19:00	
			22MAY2010	YES	8:00	YES	19:00	
			23MAY2010	YES	8:30	YES	18:00	
			24MAY2010	YES	8:15	YES	18:15	
			25MAY2010	YES	7:30	YES	18:00	
			26MAY2010	YES	7:30	YES	18:30	
			27MAY2010	YES	7:45	YES	17:50	
			28MAY2010	YES	7:50	YES	18:00	
			29MAY2010	YES	7:15	YES	19:00	
			30MAY2010	YES	7:45	YES	19:00	
			31MAY2010	YES	7:30	YES	18:45	
			01JUN2010	YES	8:00	YES	18:30	
			02JUN2010	YES	7:15	YES	17:30	
			03JUN2010	YES	7:15	YES	18:00	
			04JUN2010	YES	6:50	YES	18:30	
			05JUN2010	YES	6:45	YES	19:40	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	06JUN2010	YES	8:00	YES	17:50	
			07JUN2010	YES	8:30	YES	17:50	
			08JUN2010	YES	7:15	YES	18:00	
			09JUN2010	YES	7:45	YES	19:00	
			10JUN2010	YES	7:30	YES	18:00	
			11JUN2010	YES	7:00	YES	18:00	
			12JUN2010	YES	7:30	YES	17:45	
			13JUN2010	YES	8:30	YES	18:00	
			14JUN2010	YES	8:00	YES	17:30	
			15JUN2010	YES	6:50	YES	18:00	
			16JUN2010	YES	7:15	YES	17:45	
			17JUN2010	YES	6:15	YES	18:00	
			18JUN2010	YES	7:00	YES	19:00	
			19JUN2010	YES	8:15	YES	19:30	
			20JUN2010	YES	8:00	YES	19:30	
			21JUN2010	YES	7:45	YES	18:30	
			22JUN2010	YES	7:30	YES	18:15	
			23JUN2010	YES	7:30	YES	18:30	
			24JUN2010	YES	8:00	YES	18:15	
			25JUN2010	YES	6:45	YES	18:00	
			26JUN2010	YES	8:00	YES	18:30	
			27JUN2010	YES	8:30	YES	18:45	
			28JUN2010	YES	6:30	YES	19:00	
			29JUN2010	YES	6:30	YES	18:00	
			30JUN2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	01JUL2010	YES	7:30	YES	18:00	
			02JUL2010	YES	6:45	YES	18:15	
			03JUL2010	YES	7:30	YES	18:45	
			04JUL2010	YES	8:00	YES	17:45	
			05JUL2010	YES	7:45	YES	17:30	
			06JUL2010	YES	6:30	YES	18:00	
			07JUL2010	YES	6:45	YES	18:30	
			08JUL2010	YES	6:30	YES	17:30	
			09JUL2010	YES	7:00	YES	18:00	
			10JUL2010	YES	7:00	YES	19:00	
			11JUL2010	YES	8:00	YES	18:00	
			12JUL2010	YES	8:30	YES	18:00	
			13JUL2010	YES	6:15	YES	17:30	
			14JUL2010	YES	6:30	YES	18:00	
			15JUL2010	YES	7:00	YES	17:45	
			16JUL2010	YES	6:30	YES	18:00	
			17JUL2010	YES	6:30	YES	17:45	
			18JUL2010	YES	7:30	YES	18:00	
			19JUL2010	YES	8:00		18:30	
			20JUL2010	YES	6:15	YES	17:45	
			21JUL2010	YES	7:15	YES	17:30	
			22JUL2010	YES	7:30	YES	18:30	
			23JUL2010	YES	6:45	YES	18:00	
			24JUL2010	YES	7:45	YES	17:45	
			25JUL2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	26JUL2010	YES	6:30	YES	17:30	
			27JUL2010	YES	5:45			
			27JUL2010			YES	17:45	
			28JUL2010	YES	7:15	YES	18:15	
			29JUL2010	YES	7:30	YES	18:00	
			30JUL2010	YES	7:30	YES	17:45	
			31JUL2010	YES	8:30	YES	17:45	
			01AUG2010	YES	7:45	YES	19:45	
			02AUG2010	YES	8:00	YES	18:45	
			03AUG2010	YES	6:30	YES	18:00	
			04AUG2010	YES	6:00	YES	18:00	
			05AUG2010	YES	6:00	YES	18:30	
			06AUG2010	YES	6:15	YES	18:00	
			07AUG2010	YES	6:00	YES	18:30	
			08AUG2010	YES	8:00	YES	18:15	
			09AUG2010	YES	8:00	YES	17:30	
			10AUG2010	YES	7:00	YES	19:00	
			11AUG2010	YES	8:00	YES	17:45	
			12AUG2010	YES	8:00	YES	18:00	
			13AUG2010	YES	7:45	YES	18:00	
			14AUG2010	YES	8:00	YES	19:30	
			15AUG2010	YES	8:00	YES	18:00	
			16AUG2010	YES	7:30	YES	18:30	
			17AUG2010	YES	7:00	YES	18:30	
			18AUG2010	YES	7:45	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	19AUG2010	YES	8:00	YES	18:30	
			20AUG2010	YES	8:00	YES	18:30	
			21AUG2010	YES	7:30	YES	18:00	
			22AUG2010	YES	8:00	YES	18:30	
			23AUG2010	YES	8:00	YES	19:00	
			24AUG2010	YES	7:30	YES	18:30	
			25AUG2010	YES	6:15	YES	18:00	
			26AUG2010	YES	7:30	YES	18:00	
			27AUG2010	YES	7:30	YES	18:00	
			28AUG2010	YES	7:00	YES	20:00	
			29AUG2010	YES	8:00	YES	19:30	
			30AUG2010	YES	7:30	YES	18:30	
			31AUG2010	YES	7:30	YES	19:00	
			01SEP2010	YES	8:00	YES	18:00	
			02SEP2010	YES	6:00	YES	17:30	
			03SEP2010	YES	7:30	YES	17:45	
			04SEP2010	YES	8:00	YES	17:30	
			05SEP2010	YES	9:15	YES	18:00	
			06SEP2010	YES	8:00	YES	17:30	
			07SEP2010	YES	8:15	YES	17:30	
			08SEP2010	YES	9:00	YES	17:45	
			09SEP2010	YES	8:00	YES	18:30	
			10SEP2010	YES	7:00	YES	17:45	
			11SEP2010	YES	8:00	YES	18:00	
			12SEP2010	YES	8:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	13SEP2010	YES	7:00	YES	18:00	
			14SEP2010	YES	7:45	YES	17:30	
			15SEP2010	YES	7:00	YES	18:00	
			16SEP2010	YES	7:30	YES	18:00	
			17SEP2010	YES	8:00	YES	18:30	
			18SEP2010	YES	8:00	YES	18:00	
			19SEP2010	YES	8:00	YES	18:30	
			20SEP2010	YES	7:30	YES	18:00	
			21SEP2010	YES	7:30	YES	17:45	
			22SEP2010	YES	7:45	YES	18:15	
			23SEP2010	YES	7:00	YES	17:30	
			24SEP2010	YES	7:15	YES	17:30	
			25SEP2010	YES	8:00	YES	17:45	
			26SEP2010	YES	8:00	YES	18:30	
			27SEP2010	YES	7:30	YES	17:45	
			28SEP2010	YES	7:30	YES	17:15	
			29SEP2010	YES	7:30		18:00	
			30SEP2010	YES	6:30	YES	18:15	
			01OCT2010	YES	8:00	YES	17:30	
			02OCT2010	YES	7:30	YES	18:30	
			03OCT2010	YES	8:00	YES	18:15	
			04OCT2010	YES	8:00	YES	17:30	
			05OCT2010	YES	7:00	YES	17:15	
			06OCT2010	YES	6:30	YES	17:30	
			07OCT2010	YES	7:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	08OCT2010	YES	7:45	YES	17:30	
			09OCT2010	YES	8:15	YES	18:00	
			10OCT2010	YES	8:45	YES	18:00	
			11OCT2010	YES	7:45	YES	18:00	
			12OCT2010	YES	6:45	YES	18:00	
			13OCT2010	YES	7:00	YES	18:00	
			14OCT2010	YES	6:30	YES	18:30	
			15OCT2010	YES	7:00	YES	17:45	
			16OCT2010	YES	8:00	YES	17:45	
			17OCT2010	YES	7:00	YES	19:00	
			18OCT2010	YES	6:00	YES	18:00	
			19OCT2010	YES	6:00	YES	18:00	
			20OCT2010	YES	8:00	YES	18:00	
			21OCT2010	YES	7:15	YES	18:00	
			22OCT2010	YES	8:00	YES	17:45	
			23OCT2010	YES	8:30	YES	18:15	
			24OCT2010	YES	9:00	YES	17:30	
			25OCT2010	YES	6:45	YES	17:45	
			26OCT2010	YES	6:00	YES	18:00	
			27OCT2010	YES	7:00		17:45	
			28OCT2010	YES	7:30		17:30	
			29OCT2010	YES	7:15	YES	17:30	
			30OCT2010	YES	8:00	YES	17:30	
			31OCT2010	YES	8:00	YES	17:45	
			01NOV2010	YES	7:30	YES	18:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	018	5	02NOV2010	YES	7:00	YES	18:00	
			03NOV2010	YES	6:00	YES	18:00	
			04NOV2010	YES	8:00	YES	17:00	
			05NOV2010	YES	7:30	YES	17:30	
			06NOV2010	YES	7:45	YES	17:00	
			07NOV2010	YES	8:00	YES	18:00	
			08NOV2010	YES	7:30	YES	17:30	
			09NOV2010	YES	7:00	YES	19:30	
			10NOV2010	YES	7:30	YES	18:00	
			11NOV2010	YES	7:45	YES	17:30	
			12NOV2010	YES	7:30	YES	18:00	
			13NOV2010	YES	7:45	YES	17:30	
			14NOV2010	YES	8:00	YES	17:30	
			15NOV2010	YES	6:30	YES	17:30	
			16NOV2010	YES	8:00	YES	17:30	
			17NOV2010	YES	6:30	YES	18:00	
			18NOV2010	YES	6:15	YES	18:45	
			19NOV2010	YES	7:30	YES	17:45	
			20NOV2010	YES	8:00	YES	18:00	
			22NOV2010	YES	8:00	YES	18:30	
			23NOV2010	YES	7:00	YES		
	024	4	16AUG2010	YES	10:30	YES	18:00	
			17AUG2010	YES	8:30	YES	18:00	
			18AUG2010	YES	8:45	YES	18:36	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	19AUG2010	YES	8:30	YES	18:10	
			20AUG2010	YES	8:15	YES	18:30	
			21AUG2010	YES	8:10	YES	18:00	
			22AUG2010	YES	8:15	YES	18:00	
			23AUG2010	YES	7:10	YES	19:00	
			24AUG2010	YES	8:30	YES	18:15	
			25AUG2010	YES	8:30	YES	18:10	
			26AUG2010	YES	8:10	YES	18:30	
			27AUG2010	YES	8:45	YES	17:50	
			28AUG2010	YES	8:15	YES	18:00	
			29AUG2010	YES	8:20	YES	18:45	
			30AUG2010	YES	8:15	YES	18:05	
			31AUG2010	YES	7:30	YES	17:45	
			01SEP2010	YES	8:15	YES	18:15	
			02SEP2010	YES	8:10	YES	18:30	
			03SEP2010	YES	8:15	YES	17:50	
			04SEP2010	YES	8:10	YES	18:15	
			05SEP2010	YES	7:50	YES	18:00	
			06SEP2010	YES	8:00	YES	18:20	
			07SEP2010	YES	8:10	YES	17:55	
			08SEP2010	YES	8:15	YES	18:20	
			09SEP2010	YES	8:10	YES	18:00	
			10SEP2010	YES	8:20	YES	17:55	
			11SEP2010	YES	7:55	YES	18:00	
			12SEP2010	YES	7:55	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	13SEP2010	YES	8:00	YES	17:45	
			14SEP2010	YES	8:10	YES	17:55	
			15SEP2010	YES	7:30			
			15SEP2010			YES	17:45	
			16SEP2010	YES	8:10	YES	18:00	
			17SEP2010	YES	7:45	YES	17:30	
			18SEP2010	YES	7:55	YES	17:45	
			19SEP2010	YES	8:15	YES	18:15	
			20SEP2010	YES	8:05	YES	18:10	
			21SEP2010	YES	7:15	YES	18:30	
			22SEP2010	YES	8:10	YES	17:55	
			23SEP2010	YES	8:15	YES	17:30	
			24SEP2010	YES	7:45	YES	17:30	
			25SEP2010	YES	8:10	YES	17:55	
			26SEP2010	YES	8:00	YES	17:50	
			27SEP2010	YES	8:15	YES	18:00	
			28SEP2010	YES	8:30	YES	18:15	
			29SEP2010	YES	8:20	YES	17:55	
			30SEP2010	YES	7:45	YES	18:10	
			01OCT2010	YES	8:05	YES	18:05	
			02OCT2010	YES	7:50	YES	17:55	
			03OCT2010	YES	7:55	YES	18:15	
			04OCT2010	YES	8:10	YES	17:50	
			05OCT2010	YES	8:15	YES	18:00	
			06OCT2010	YES	7:55	YES	18:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	07OCT2010	YES	7:45	YES	17:55	
			08OCT2010	YES	8:30	YES	18:20	
			08OCT2010	YES	8:10	YES	18:00	
			09OCT2010	YES	8:00	YES	18:15	
			10OCT2010	YES	8:45	YES	18:30	
			11OCT2010	YES	8:00	YES	18:00	
			12OCT2010	YES	8:15	YES	17:45	
			13OCT2010	YES	7:55	YES	17:50	
			14OCT2010	YES	8:10	YES	18:05	
			15OCT2010	YES	8:20	YES	18:15	
			16OCT2010	YES	8:10	YES	17:55	
			17OCT2010	YES	8:05	YES	17:45	
			18OCT2010	YES	8:50	YES	18:05	
			19OCT2010	YES	8:15	YES	17:55	
			20OCT2010	YES	8:10	YES	18:30	
			21OCT2010	YES	7:55	YES	18:05	
			22OCT2010	YES	8:15	YES	18:10	
			23OCT2010	YES	8:00	YES	17:50	
			24OCT2010	YES	8:05	YES	17:55	
			25OCT2010	YES	7:45	YES	18:30	
			26OCT2010	YES	7:55	YES	18:15	
			27OCT2010	YES	8:15	YES	18:05	
			28OCT2010	YES	8:30	YES	17:55	
			29OCT2010	YES	8:15	YES	18:05	
			30OCT2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	31OCT2010	YES	7:50	YES	17:55	
			01NOV2010	YES	8:15	YES	18:00	
			02NOV2010	YES	8:00	YES	18:10	
			03NOV2010	YES	7:55	YES	18:15	
			04NOV2010	YES	8:20	YES	17:50	
			05NOV2010	YES	8:15	YES	17:55	
			06NOV2010	YES	7:55	YES	18:00	
			07NOV2010	YES	8:15	YES	18:05	
			08NOV2010	YES	8:00	YES	17:50	
			09NOV2010	YES	7:55	YES	18:05	
			10NOV2010	YES	7:15			
			11NOV2010	YES	8:30	YES	17:15	
			12NOV2010	YES	9:00	YES	17:45	
			13NOV2010	YES	8:50	YES	18:00	
			14NOV2010	YES	8:40	YES	17:15	
			15NOV2010	YES	8:45	YES	18:15	
			16NOV2010	YES	7:50	YES	17:15	
			17NOV2010	YES	8:05	YES	17:30	
			18NOV2010	YES	7:45	YES	17:15	
			19NOV2010	YES	8:20	YES	18:00	
			20NOV2010	YES	8:15	YES	17:30	
			21NOV2010	YES	8:20	YES	17:10	
			22NOV2010	YES	8:45	YES	18:05	
			23NOV2010	YES	7:55	YES	17:50	
			24NOV2010	YES	8:00	YES	17:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	25NOV2010	YES	8:10	YES	18:10	
			26NOV2010	YES	8:15	YES	18:20	
			27NOV2010	YES	8:45	YES	18:05	
			28NOV2010	YES	8:00	YES	17:55	
			29NOV2010	YES	8:30	YES	18:10	
			30NOV2010	YES	8:45	YES	18:15	
			01DEC2010	YES	7:50	YES	17:55	
			02DEC2010	YES	7:45	YES	17:45	
			03DEC2010	YES	8:10	YES	18:15	
			04DEC2010	YES	8:20	YES	18:25	
			05DEC2010	YES	8:15	YES	18:00	
			06DEC2010	YES	8:10	YES	17:55	
			07DEC2010	YES	7:50	YES	17:50	
			08DEC2010	YES	8:30	YES	18:15	
			09DEC2010	YES	8:15	YES	18:08	
			10DEC2010	YES	8:20	YES	18:10	
			11DEC2010	YES	8:00	YES	17:50	
			12DEC2010	YES	7:45	YES	18:05	
			13DEC2010	YES	7:50	YES	18:15	
			14DEC2010	YES	8:30	YES	18:30	
			15DEC2010	YES	8:00	YES	18:15	
			16DEC2010	YES	8:05	YES	17:50	
			17DEC2010	YES	8:15	YES	18:00	
			18DEC2010	YES	8:30	YES	18:15	
			19DEC2010	YES	8:45	YES	19:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	20DEC2010	YES	7:50	YES	18:45	
			21DEC2010	YES	8:15	YES	18:55	
			22DEC2010	YES	8:20	YES	19:10	
			23DEC2010	YES	7:50	YES	18:15	
			24DEC2010	YES	7:30	YES	17:00	
			25DEC2010	YES	8:50	YES	18:15	
			26DEC2010	YES	8:00	YES	18:30	
			27DEC2010	YES	8:10	YES	18:15	
			28DEC2010	YES	8:30	YES	18:30	
			29DEC2010	YES	8:45	YES	18:50	
			30DEC2010	YES	8:00	YES	18:05	
			31DEC2010	YES	8:45	YES	19:30	
			01JAN2011	YES	9:15	YES	17:45	
			02JAN2011	YES	8:15	YES	17:55	
			03JAN2011	YES	7:45	YES	17:15	
			04JAN2011	YES	9:00	YES	17:30	
			05JAN2011	YES	8:45	YES	17:55	
			06JAN2011	YES	8:50	YES	18:05	
			07JAN2011	YES	8:30	YES	18:15	
			08JAN2011	YES	7:55	YES	17:30	
			09JAN2011	YES	8:15	YES	17:45	
			10JAN2011	YES	8:30	YES	17:30	
			11JAN2011	YES	8:50	YES	18:10	
			12JAN2011	YES	8:55	YES	18:15	
			13JAN2011	YES	8:45	YES	17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	14JAN2011	YES	8:30	YES	17:30	
			15JAN2011	YES	9:00	YES	18:10	
			16JAN2011	YES	8:50	YES	17:50	
			17JAN2011	YES	8:15	YES	17:30	
			18JAN2011	YES	8:45	YES	17:50	
			19JAN2011	YES	9:05	YES	18:30	
			20JAN2011	YES	9:15	YES	18:15	
			21JAN2011	YES	8:50	YES	17:45	
			22JAN2011	YES	8:45	YES	17:55	
			23JAN2011	YES	8:30	YES	17:30	
			24JAN2011	YES	8:50	YES	18:00	
			25JAN2011	YES	8:45	YES	18:15	
			26JAN2011	YES	9:10	YES	18:05	
			27JAN2011	YES	8:30	YES	18:45	
			28JAN2011	YES	8:55	YES	17:30	
			29JAN2011	YES	8:40	YES	17:45	
			30JAN2011	YES	8:50	YES	17:55	
			31JAN2011	YES	8:50	YES	17:55	
			01FEB2011	YES	8:30	YES	17:50	
			02FEB2011	YES	6:30			
			02FEB2011			YES	18:00	
			03FEB2011	YES	8:45	YES	17:55	
			04FEB2011	YES	8:15	YES	18:15	
			05FEB2011	YES	8:10	YES	17:30	
			06FEB2011	YES	8:20	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	07FEB2011	YES	8:50	YES	17:50	
			08FEB2011	YES	7:50	YES	18:05	
			09FEB2011	YES	8:00	YES	18:15	
			10FEB2011	YES	8:30	YES	18:05	
			11FEB2011	YES	9:10	YES	17:50	
			12FEB2011	YES	8:45		17:55	
			13FEB2011	YES	9:05	YES	18:15	
			14FEB2011	YES	8:50	YES	17:30	
			15FEB2011	YES	8:45	YES	17:45	
			16FEB2011	YES	8:40	YES	17:50	
			17FEB2011	YES	9:00	YES	17:55	
			18FEB2011	YES	8:30	YES	17:30	
			19FEB2011	YES	8:50	YES	18:10	
			20FEB2011	YES	8:55	YES	17:50	
			21FEB2011	YES	8:40	YES	17:30	
			22FEB2011	YES	8:45	YES	17:45	
			23FEB2011	YES	8:30	YES	17:30	
			24FEB2011	YES	9:00	YES	17:55	
			25FEB2011	YES	8:55	YES	18:05	
			26FEB2011	YES	8:50	YES	17:50	
			27FEB2011	YES	8:45	YES	17:30	
			28FEB2011	YES	8:55	YES	17:45	
			01MAR2011	YES	8:10	YES	17:55	
			02MAR2011	YES	7:55	YES	18:05	
			03MAR2011	YES	8:15	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	04MAR2011	YES	8:30	YES	17:45	
			05MAR2011	YES	8:20	YES	17:50	
			06MAR2011	YES	8:30	YES	18:15	
			07MAR2011	YES	8:15	YES	18:10	
			08MAR2011	YES	7:50	YES	17:50	
			09MAR2011	YES	8:00	YES	18:10	
			10MAR2011	YES	7:55	YES	18:10	
			11MAR2011	YES	8:15	YES	18:05	
			12MAR2011	YES	8:30	YES	18:30	
			13MAR2011	YES	8:45	YES	18:30	
			14MAR2011	YES	9:50	YES	17:55	
			15MAR2011	YES	9:45	YES	18:20	
			16MAR2011	YES	9:05	YES	18:00	
			17MAR2011	YES	8:30	YES	17:30	
			18MAR2011	YES	8:45	YES	17:50	
			19MAR2011	YES	8:00	YES	18:05	
			20MAR2011	YES	8:15	YES	18:10	
			21MAR2011	YES	7:50	YES	18:05	
			22MAR2011	YES	7:45	YES	18:30	
			23MAR2011	YES	8:10	YES	17:30	
			24MAR2011	YES	8:30	YES	17:45	
			25MAR2011	YES	7:30	YES	18:30	
			26MAR2011	YES	8:00	YES	17:45	
			27MAR2011	YES	8:15	YES	17:50	
			28MAR2011	YES	7:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	29MAR2011	YES	8:00	YES	18:50	
			30MAR2011	YES	8:45	YES	18:00	
			31MAR2011	YES	8:50	YES	17:50	
			01APR2011	YES	7:45	YES	18:30	
			02APR2011	YES	7:55	YES	18:45	
			03APR2011	YES	8:15	YES	18:00	
			04APR2011	YES	8:30	YES	17:45	
			05APR2011	YES	8:10	YES	18:10	
			06APR2011	YES	8:30	YES	17:50	
			07APR2011	YES	7:50	YES	17:55	
			08APR2011	YES	8:30	YES	18:15	
			09APR2011	YES	8:45	YES	18:30	
			10APR2011	YES	8:30	YES	17:50	
			11APR2011	YES	8:45	YES	18:15	
			12APR2011	YES	8:50	YES	18:30	
			13APR2011	YES	9:00	YES	18:45	
			14APR2011	YES	7:50	YES	17:55	
			15APR2011	YES	8:30	YES	18:05	
			16APR2011	YES	7:55	YES	17:50	
			17APR2011	YES	8:05	YES	18:30	
			18APR2011	YES	6:30			
			18APR2011			YES	18:00	
			19APR2011	YES	9:05	YES	18:15	
			20APR2011	YES	8:45	YES	18:00	
			21APR2011	YES	8:05	YES	17:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	22APR2011	YES	7:50	YES	18:30	
			23APR2011	YES	8:10	YES	18:15	
			24APR2011	YES	8:15	YES	17:50	
			25APR2011	YES	7:45	YES	19:15	
			26APR2011	YES	8:45	YES	18:45	
			27APR2011	YES	8:10	YES	17:45	
			28APR2011	YES	8:30	YES	18:10	
			29APR2011	YES	8:15	YES	18:30	
			30APR2011	YES	7:50	YES	18:45	
			01MAY2011	YES	8:20	YES	18:55	
			02MAY2011	YES	8:15	YES	18:30	
			03MAY2011	YES	9:05	YES	18:45	
			04MAY2011	YES	8:50	YES	18:15	
			05MAY2011	YES	9:10	YES	17:45	
			06MAY2011	YES	8:10	YES	18:15	
			07MAY2011	YES	8:00	YES	18:30	
			08MAY2011	YES	8:30	YES	17:50	
			09MAY2011	YES	8:15	YES	18:10	
			10MAY2011	YES	7:50	YES	17:50	
			11MAY2011	YES	8:15	YES	18:10	
			12MAY2011	YES	8:30	YES	18:45	
			13MAY2011	YES	8:45	YES	18:05	
			14MAY2011	YES	7:50	YES	18:00	
			15MAY2011	YES	8:00	YES	18:00	
			16MAY2011	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	18MAY2011	YES	8:30	YES	18:00	
			19MAY2011	YES	8:14	YES	18:20	
			20MAY2011	YES	8:00	YES	18:00	
			21MAY2011	YES	7:30	YES	18:00	
			22MAY2011	NO				
			23MAY2011	NO				
			24MAY2011	NO				
			25MAY2011	NO				
			26MAY2011	NO				
			27MAY2011	NO				
			28MAY2011	NO				
			29MAY2011	YES	8:50	YES	18:15	
			30MAY2011	YES	9:10	YES	18:30	
			31MAY2011	YES	8:30	YES	18:45	
			01JUN2011	YES	8:10	YES	18:00	
			02JUN2011	YES	8:45	YES	18:15	
			03JUN2011	YES	8:15	YES	17:55	
			04JUN2011	YES	8:45	YES	8:10	
			05JUN2011	YES	8:05	YES	18:10	
			06JUN2011	YES	8:15	YES	18:30	
			07JUN2011	YES	8:30	YES	17:50	
			08JUN2011	YES	8:15	YES	17:55	
			09JUN2011	YES	8:20	YES	17:50	
			10JUN2011	YES	8:20	YES	18:05	
			11JUN2011	YES	8:30	YES	17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	12JUN2011	YES	7:50	YES	17:30	
			13JUN2011	YES	8:15	YES	18:30	
			14JUN2011	YES	8:30	YES	18:15	
			15JUN2011	YES	8:35	YES	18:00	
			16JUN2011	YES	8:10	YES	18:45	
			17JUN2011	YES	8:45	YES	17:55	
			18JUN2011	YES	9:00	YES	18:05	
			19JUN2011	YES	8:50	YES	18:15	
			20JUN2011	YES	8:45	YES	18:30	
			21JUN2011	YES	7:00	YES	19:30	
			22JUN2011	YES	8:50	YES	18:15	
			23JUN2011	YES	8:45	YES	17:50	
			24JUN2011	YES	8:50	YES	18:15	
			25JUN2011	YES	9:15	YES	18:30	
			26JUN2011	YES	9:00	YES	19:15	
			27JUN2011	YES	10:15	YES	20:10	
			28JUN2011	YES	9:30	YES	19:05	
			29JUN2011	YES	8:55	YES	18:50	
			30JUN2011	YES	8:55	YES	19:00	
			01JUL2011	YES	8:50	YES	19:15	
			02JUL2011	YES	8:30	YES	18:50	
			03JUL2011	YES	8:45	YES	18:35	
			04JUL2011	YES	8:55	YES	19:10	
			05JUL2011	YES	9:05	YES	19:15	
			06JUL2011	YES	8:30	YES	18:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	08JUL2011	YES	8:45	YES	18:45	
			09JUL2011	YES	8:55	YES	18:50	
			10JUL2011	YES	8:30	YES	18:50	
			11JUL2011	YES	8:45	YES	18:55	
			12JUL2011	YES	7:30	YES	19:15	
			13JUL2011	YES	9:05	YES	19:05	
			14JUL2011	YES	9:15	YES	18:50	
			15JUL2011	YES	9:10	YES	18:45	
			16JUL2011	YES	8:15	YES	18:50	
			17JUL2011	YES	8:30	YES	18:30	
			18JUL2011	YES	8:45	YES	18:55	
			19JUL2011	YES	8:50	YES	18:55	
			20JUL2011	YES	8:30	YES	18:30	
			21JUL2011	YES	8:55	YES	18:50	
			22JUL2011	YES	7:45	YES	18:45	
			23JUL2011	YES	8:15	YES	19:10	
			24JUL2011	YES	8:30	YES	18:50	
			25JUL2011	YES	8:35	YES	19:15	
			26JUL2011	YES	8:50	YES	18:30	
			27JUL2011	YES	8:45	YES	19:10	
			28JUL2011	YES	8:50	YES	18:30	
			29JUL2011	YES	8:45	YES	18:55	
			30JUL2011	YES	9:05	YES	19:05	
			31JUL2011	YES	8:30	YES	18:15	
			01AUG2011	YES	8:45	YES	18:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	024	4	02AUG2011	YES	9:10	YES	19:10	
			03AUG2011	YES	8:40	YES	18:50	
			04AUG2011	YES	8:50	YES	18:30	
			05AUG2011	YES	8:30	YES	18:40	
			06AUG2011	YES	8:10	YES	17:55	
			07AUG2011	YES	8:15	YES	18:15	
			08AUG2011	YES	6:30			
	028	20	27NOV2010	YES	7:45	YES	18:00	
			28NOV2010	YES	6:30	YES	17:00	
			29NOV2010	YES	6:00	YES	17:00	
			30NOV2010		6:30	YES	17:00	
			01DEC2010		6:45	YES	17:00	
			02DEC2010		6:30	YES	17:00	
			03DEC2010		5:45		17:30	
			04DEC2010	YES	7:45	YES	18:00	
			05DEC2010	YES	7:00	YES	17:00	
			06DEC2010	YES	7:15	YES	17:00	
			07DEC2010	YES	7:00	YES	17:30	
			08DEC2010	YES	6:45	YES	17:00	
			09DEC2010	YES	7:00	YES	18:30	
			10DEC2010	YES	7:15	YES	17:30	
			11DEC2010	YES	7:15	YES	17:30	
			12DEC2010	YES	6:00	YES	17:00	
			13DEC2010	YES	7:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	14DEC2010	YES	7:00	YES	20:00	
			15DEC2010	YES	6:15	YES	17:30	
			16DEC2010	YES	6:40	YES	20:00	
			17DEC2010	YES	7:00	YES	19:00	
			18DEC2010	YES	6:00		19:00	
			19DEC2010	YES	7:00		19:30	
			20DEC2010	YES	7:00	YES	19:30	
			21DEC2010	YES	6:00			
			22DEC2010	YES	7:00	YES	18:00	
			23DEC2010	YES	7:00	YES	18:00	
			24DEC2010	YES	7:00	YES	18:00	
			25DEC2010	YES	7:00	YES	18:00	
			26DEC2010	YES	7:00	YES	18:00	
			27DEC2010	YES	7:00	YES	18:00	
			28DEC2010	YES	7:00	YES	18:00	
			29DEC2010	YES	7:00	YES	18:00	
			30DEC2010	YES	7:00	YES	18:00	
			31DEC2010	YES	6:30	YES	17:30	
			01JAN2011	YES	7:00	YES	17:10	
			02JAN2011	YES	7:00	YES	17:30	
			03JAN2011	YES	6:15	YES	17:30	
			04JAN2011	YES	6:15	YES	17:15	
			05JAN2011	YES	7:00	YES	17:00	
			06JAN2011	YES	7:00	YES	18:45	
			07JAN2011	YES	7:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	08JAN2011	YES	7:00	YES	16:45	
			09JAN2011	YES	7:00	YES	16:45	
			10JAN2011	YES	6:15	YES	16:45	
			11JAN2011	YES	6:15	YES	16:45	
			12JAN2011	YES	6:00	YES	16:45	
			13JAN2011	YES	7:00	YES	16:45	
			14JAN2011	YES	7:00	YES	16:45	
			15JAN2011	YES	6:00	YES	16:30	
			16JAN2011	YES	5:00	YES	16:45	
			17JAN2011	YES	6:30	YES	16:30	
			18JAN2011	YES	6:30	YES	16:30	
			19JAN2011	YES	5:30	YES	16:30	
			20JAN2011	YES	6:00	YES	16:30	
			21JAN2011	YES	7:00	YES	16:30	
			22JAN2011	YES	7:00	YES	16:40	
			23JAN2011	YES	6:30	YES	17:20	
			24JAN2011	YES	6:00	YES	17:00	
			25JAN2011	YES	6:00	YES	16:30	
			26JAN2011	YES	6:00	YES	16:30	
			27JAN2011	YES	5:00	YES	17:30	
			28JAN2011	YES	6:00	YES	17:30	
			29JAN2011	YES	6:00	YES	17:30	
			30JAN2011	YES	6:00	YES	16:30	
			31JAN2011	YES	5:00	YES	16:30	
			01FEB2011	YES	5:00	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	02FEB2011	YES	6:30	YES	17:00	
			03FEB2011	YES	5:00	YES	19:00	
			04FEB2011	YES	5:30	YES	16:30	
			05FEB2011	YES	6:00	YES	16:45	
			06FEB2011	YES	6:00	YES	17:00	
			07FEB2011	YES	6:00	YES	17:30	
			08FEB2011	YES	6:00	YES	17:00	
			09FEB2011	YES	7:00	YES	17:30	
			10FEB2011	YES	7:00	YES	16:30	
			11FEB2011	YES	7:00	YES	17:30	
			12FEB2011	YES	7:30	YES	17:30	
			13FEB2011	YES	6:00	YES	17:30	
			14FEB2011	YES	5:30	YES	17:20	
			15FEB2011	YES	4:30	YES	18:20	
			16FEB2011	YES	4:50	YES	17:30	
			17FEB2011	YES	4:45	YES	17:30	
			18FEB2011	YES	4:45	YES	17:30	
			19FEB2011	YES	5:30	YES	17:30	
			20FEB2011	YES	4:50	YES	19:30	
			21FEB2011	YES	5:30	YES	17:00	
			22FEB2011	YES	5:30			
			22FEB2011	YES			17:30	
			23FEB2011	YES	5:30	YES	17:30	
			24FEB2011	YES	6:00	YES	17:30	
			25FEB2011	YES	6:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	26FEB2011	YES	5:30	YES	17:00	
			27FEB2011	YES	5:30	YES	17:30	
			28FEB2011		5:30		17:00	
			01MAR2011		7:00		18:00	
			02MAR2011		7:30		18:00	starker Husten
			03MAR2011	YES	7:30	YES	18:00	starker Husten, starke Verköhlung
			04MAR2011	YES	7:00	YES	18:30	
			05MAR2011	YES	7:00	YES	18:00	Krankenhaus Müzzzuschlag
			06MAR2011	YES	7:30	YES	16:30	Krankenhaus Müzzzuschlag
			07MAR2011	YES	7:30	YES	16:30	Krankenhaus Müzzzuschlag
			08MAR2011	YES	7:30	YES	16:30	Krankenhaus Müzzzuschlag
			09MAR2011	YES	7:30	YES	16:30	Krankenhaus Müzzzuschlag
			10MAR2011	YES	7:30	YES	16:30	Krankenhaus Müzzzuschlag
			11MAR2011	YES	7:30	YES	16:30	Krankenhaus Müzzzuschlag
			12MAR2011	YES	6:00	YES	17:30	zu Hause
			13MAR2011	YES	7:00	YES	17:30	
			14MAR2011	YES	6:30	YES	17:00	
			15MAR2011	YES	10:00	YES	17:00	
			16MAR2011	YES	5:30	YES	17:00	
			17MAR2011	YES	4:30	YES	17:00	
			18MAR2011	YES	7:00	YES	17:00	
			19MAR2011	YES	5:00	YES	17:00	
			20MAR2011	YES	7:00	YES	19:00	
			21MAR2011	YES	7:00	YES	17:00	
			22MAR2011	YES	5:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	23MAR2011	YES	5:30	YES	17:00	
			24MAR2011	YES	5:00	YES	17:00	
			25MAR2011	YES	5:00	YES	18:00	
			26MAR2011	YES	5:30	YES	17:00	
			27MAR2011	YES	5:00	YES	17:00	
			28MAR2011	YES	7:00	YES	18:00	
			29MAR2011	YES	5:30	YES	18:00	
			30MAR2011	YES	5:00	YES	17:00	
			31MAR2011	YES	5:00	YES	17:00	
			01APR2011	YES	7:00	YES	18:00	
			02APR2011	YES	7:00	YES	17:00	
			03APR2011	YES	6:00	YES	17:00	Kaprun
			04APR2011	YES	7:00	YES	17:30	Kaprun
			05APR2011	YES	7:00	YES	17:30	Kaprun
			06APR2011	YES	7:00	YES	17:30	Kaprun
			07APR2011	YES	7:00	YES	17:30	Kaprun
			08APR2011	YES	7:00	YES	17:30	
			09APR2011	YES	7:30	YES	17:00	
			10APR2011	YES	6:00	YES	18:00	
			11APR2011	YES	7:30	YES	18:00	
			12APR2011	YES	7:00	YES	17:00	
			13APR2011	YES	6:00	YES	17:00	
			14APR2011	YES	6:00	YES	17:00	
			15APR2011	YES	6:00	YES	17:00	
			16APR2011	YES	6:00	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	17APR2011	YES	6:00	YES	17:00	
			18APR2011	YES	6:00	YES	17:00	
			19APR2011	YES	6:00	YES	17:00	
			20APR2011	YES	6:00	YES	17:00	
			21APR2011	YES	6:30	YES	17:00	
			22APR2011	YES	6:30	YES	17:00	
			23APR2011	YES	5:00	YES	17:00	
			24APR2011	YES	6:00	YES	16:30	
			25APR2011	YES	6:30	YES	16:30	
			26APR2011	YES	6:00		17:00	
			27APR2011	YES	5:00	YES	17:00	
			28APR2011	YES	6:00	YES	17:00	
			29APR2011	YES	6:00	YES	17:00	
			30APR2011	YES	6:00	YES	17:00	
			01MAY2011	YES	6:00	YES	17:00	
			02MAY2011	YES	6:00	YES	17:00	
			03MAY2011	YES	6:00	YES	16:30	
			04MAY2011	YES	7:00	YES	17:30	
			05MAY2011	YES	5:30	YES	18:00	
			06MAY2011	YES	5:00	YES	16:30	
			07MAY2011	YES	6:30	YES	17:00	
			08MAY2011	YES	5:30	YES	16:30	
			09MAY2011	YES	6:00	YES	16:30	
			10MAY2011	YES	5:30	YES	17:00	
			11MAY2011	YES	5:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	12MAY2011	YES	5:00	YES	17:00	
			13MAY2011	YES	5:30	YES	16:30	
			14MAY2011	YES	5:30	YES	16:30	
			15MAY2011	YES	5:30	YES	16:30	
			16MAY2011	YES	4:30	YES	16:30	
			17MAY2011	YES	6:00	YES	17:00	
			18MAY2011	YES	3:30	YES	17:00	ab Laßnitzhöhe
			19MAY2011	YES	6:30	YES	16:30	ab Laßnitzhöhe
			20MAY2011	YES	6:30	YES	16:30	ab Laßnitzhöhe
			21MAY2011	YES	6:30	YES	16:30	
			22MAY2011	YES	6:00	YES	17:00	
			23MAY2011	YES	6:00	YES	16:30	
			24MAY2011	YES	6:00			
			24MAY2011			YES	18:30	
			25MAY2011	YES	6:30	YES	16:15	
			26MAY2011	YES	5:00	YES	16:30	
			27MAY2011	YES	5:30	YES	16:30	
			28MAY2011	YES	7:00	YES	16:30	
			29MAY2011	YES	7:00	YES	16:30	
			30MAY2011	YES	6:30	YES	16:30	
			31MAY2011	YES	7:00	YES	16:30	
			01JUN2011	YES	6:30	YES	16:30	
			02JUN2011	YES	7:00	YES	16:30	
			03JUN2011	YES	6:30	YES	17:00	
			04JUN2011	YES	5:30	YES	16:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	05JUN2011	YES	7:00	YES	17:00	
			06JUN2011	YES	7:30	YES	16:30	
			07JUN2011	YES	6:30	YES	18:00	
			08JUN2011	YES	6:30	YES	16:30	
			09JUN2011	YES	6:30	YES	16:30	
			10JUN2011	YES	5:30	YES	16:45	
			11JUN2011	YES	6:30	YES	16:30	
			12JUN2011	YES	7:00	YES	18:30	
			13JUN2011	YES	7:00	YES	16:30	
			14JUN2011	YES	5:00	YES	16:30	
			15JUN2011	YES	6:00	YES	16:30	
			16JUN2011	YES	5:00	YES	16:30	
			17JUN2011	YES	5:30	YES	16:30	
			18JUN2011	YES	7:00	YES	16:00	
			19JUN2011	YES	5:00	YES	16:30	
			20JUN2011	YES	4:30	YES	16:30	
			21JUN2011	YES	5:00	YES	17:00	
			22JUN2011	YES	6:30	YES	18:00	
			23JUN2011	YES	4:30	YES	19:00	
			24JUN2011	YES	4:30	YES	16:30	
			25JUN2011	YES	5:00	YES	16:30	
			26JUN2011	YES	5:00	YES	16:30	
			27JUN2011	YES	5:00	YES	17:00	
			28JUN2011	YES	5:00	YES	17:00	
			29JUN2011	YES	5:00	YES	16:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	30JUN2011	YES	5:00	YES	16:30	
			01JUL2011	YES	7:00	YES	18:30	
			02JUL2011	YES	8:00	YES	18:00	
			03JUL2011	YES	6:00	YES	17:00	
			04JUL2011	YES	6:00	YES	17:00	
			05JUL2011	YES	6:00	YES	16:30	
			06JUL2011	YES	5:30	YES	17:00	
			07JUL2011	YES	5:30	YES	17:00	
			08JUL2011	YES	5:00	YES	16:30	
			09JUL2011	YES	5:00	YES	17:00	
			10JUL2011	YES	5:00	YES	17:00	
			11JUL2011	YES	6:00	YES	17:00	
			12JUL2011	YES	5:00	YES	17:00	
			13JUL2011	YES	5:00	YES	20:00	
			14JUL2011	YES	5:00	YES	16:30	
			15JUL2011	YES	5:00	YES	18:00	
			16JUL2011	YES	4:00	YES		
			17JUL2011	YES	5:00	YES	16:30	
			18JUL2011	YES	5:00	YES	16:30	
			19JUL2011	YES	6:00	YES	16:30	
			20JUL2011	YES	5:00	YES	16:30	
			21JUL2011	YES	6:00	YES	17:00	
			22JUL2011	YES	5:30	YES	16:30	
			23JUL2011	YES	6:00	YES	16:30	
			24JUL2011	YES	5:30	YES	16:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	25JUL2011	YES	5:30	YES	16:00	
			26JUL2011	YES	5:00	YES	16:30	
			27JUL2011	YES	6:30	YES	18:45	
			28JUL2011	YES	5:00	YES	16:30	
			29JUL2011	YES	5:00	YES	16:30	
			30JUL2011	YES	5:00	YES	17:00	
			31JUL2011	YES	5:30	YES	17:30	
			01AUG2011	YES	5:00	YES	19:00	
			02AUG2011	YES	5:00	YES	16:30	
			03AUG2011	YES	6:00	YES	17:00	
			04AUG2011	YES	5:00	YES	17:00	
			05AUG2011	YES	5:00	YES	16:15	
			06AUG2011	YES	6:30	YES	16:30	
			07AUG2011	YES	5:00	YES	16:30	
			08AUG2011	YES	5:00	YES	17:00	
			09AUG2011	YES	6:00		17:00	
			10AUG2011	YES	5:30	YES	16:30	
			11AUG2011	YES	5:00	YES	17:00	
			12AUG2011	YES	5:00	YES	17:00	
			13AUG2011	YES	5:00	YES	17:00	
			14AUG2011	YES	4:30	YES	16:30	
			15AUG2011	YES	5:00	YES	16:30	
			16AUG2011	YES	6:00	YES	16:30	
			17AUG2011	YES	5:00	YES	16:30	
			18AUG2011	YES	4:30	YES	16:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	19AUG2011	YES	6:30	YES	16:30	
			20AUG2011	YES	6:00	YES	17:00	
			21AUG2011	YES	4:00	YES	17:00	
			22AUG2011	YES	4:30	YES	16:30	
			23AUG2011	YES	4:30	YES	16:30	
			24AUG2011	YES	4:30	YES	16:30	
			25AUG2011			YES	17:30	(in Graz gewesen)
			25AUG2011	YES	5:30			
			26AUG2011	YES	5:00	YES	17:00	
			27AUG2011	YES	7:30	YES	16:30	
			28AUG2011	YES	5:00	YES	16:30	
			29AUG2011	YES	4:30	YES	16:00	
			30AUG2011	YES	4:30	YES	16:30	
			31AUG2011	YES	6:00	YES	16:30	
			01SEP2011	YES	4:30	YES	17:00	
			02SEP2011	YES	3:30	YES	16:00	
			03SEP2011	YES	6:30	YES	17:00	
			04SEP2011	YES	6:00	YES	17:00	
			05SEP2011	YES	4:30	YES	17:00	
			06SEP2011	YES	5:00	YES	17:00	
			07SEP2011	YES	4:30	YES	17:30	
			08SEP2011	YES	5:00		16:30	
			09SEP2011	YES	7:00	YES	16:30	
			10SEP2011	YES	6:00	YES	19:00	
			11SEP2011	YES	5:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	12SEP2011	YES	5:00	YES	17:00	
			13SEP2011	YES	5:30	YES	17:00	
			14SEP2011	YES	5:00	YES	17:00	
			15SEP2011	YES	5:00	YES	16:30	
			16SEP2011	YES	6:00	YES	17:00	
			17SEP2011	YES	6:30	YES	17:00	
			18SEP2011	YES	5:00	YES	17:00	
			19SEP2011	YES	6:30	YES	16:30	
			20SEP2011	YES	6:30	YES	16:30	
			21SEP2011	YES	4:30	YES	18:20	Grossarl Kathrin
			22SEP2011	YES	7:00	YES	18:20	Grossarl Kathrin
			23SEP2011	YES	7:00	YES	18:20	Grossarl Kathrin
			24SEP2011	YES	7:00	YES	18:20	Grossarl Kathrin
			25SEP2011	YES	7:00	YES	18:20	Grossarl Kathrin
			26SEP2011	YES	7:00	YES	18:20	Grossarl Kathrin
			27SEP2011	YES	7:00	YES	18:20	Grossarl Kathrin/zu Hause
			28SEP2011	YES	8:00	YES	17:50	
			29SEP2011	YES	6:00	YES	17:50	
			30SEP2011	YES	7:00	YES	17:15	
			01OCT2011	YES	7:00	YES	17:00	
			02OCT2011	YES	7:00	YES	17:00	
			03OCT2011	YES	7:00	YES	17:00	
			04OCT2011	YES	6:00	YES	17:00	
			05OCT2011	YES	6:00	YES	17:00	
			06OCT2011	YES	7:00	YES	17:00	

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Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	07OCT2011	YES	6:00	YES	16:30	
			08OCT2011	YES	6:00	YES	19:00	
			09OCT2011	YES	7:00	YES	16:30	
			10OCT2011	YES	6:00	YES	16:30	
			11OCT2011	YES	6:00	YES	17:00	
			12OCT2011	YES	7:00	YES	17:00	
			13OCT2011	YES	7:00	YES	17:00	
			14OCT2011	YES	7:00	YES	17:00	
			15OCT2011	YES	8:00	YES	16:30	
			16OCT2011	YES	6:00	YES	16:30	
			17OCT2011	YES	7:00	YES	16:30	
			18OCT2011	YES	7:00	YES	17:00	
			19OCT2011	YES	6:30	YES	16:30	
			20OCT2011	YES		YES	16:30	
			21OCT2011	YES	7:00	YES	16:30	
			22OCT2011	YES	5:30	YES	17:00	
			23OCT2011	YES	7:00	YES	18:00	
			24OCT2011	YES	5:00	YES	16:30	
			25OCT2011	YES	5:30	YES	16:00	
			26OCT2011	YES	6:00	YES	17:00	
			27OCT2011	YES	6:00	YES	17:00	
			28OCT2011	YES	7:00	YES	17:00	
			29OCT2011	YES	6:00	YES	16:30	
			30OCT2011	YES	6:00	YES	17:00	
			31OCT2011	YES	6:00	YES	16:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	028	20	01NOV2011	YES	7:00	YES	16:30	
			02NOV2011	YES	6:00	YES	17:00	
			03NOV2011	YES	6:00	YES	17:00	
			04NOV2011	YES	6:30	YES	16:30	
			05NOV2011	YES	7:00	YES	16:30	
			06NOV2011	YES	6:00	YES	16:30	
			07NOV2011	YES	6:00	YES	16:30	
			08NOV2011	YES	6:00	YES	16:30	
			09NOV2011	YES	6:00	YES	16:30	
			10NOV2011	YES	6:00	YES	16:30	
			11NOV2011	YES	6:00	YES	16:30	
			12NOV2011	YES	6:00	YES	18:30	
			13NOV2011	YES	6:00	YES	16:30	
			14NOV2011	YES	7:00	YES	16:30	
			15NOV2011	YES	7:00	YES	17:00	
			16NOV2011	YES	7:00	YES	17:00	
			17NOV2011	YES	6:00	YES	16:30	
			18NOV2011	YES	7:00	YES	16:30	
			19NOV2011	YES	6:00	YES	16:30	
			20NOV2011	YES	5:30	YES	16:30	
			21NOV2011	YES	7:00	YES	16:30	
			22NOV2011	YES	6:00	YES	16:30	
			23NOV2011	YES	6:00	YES	16:30	
			24NOV2011	YES	5:30			

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	29JAN2010	YES	10:20	YES	18:30	
			30JAN2010	YES	11:00	YES	20:30	
			31JAN2010	YES	10:00	YES	18:30	
			01FEB2010	YES	10:00	YES	18:30	
			02FEB2010	YES	9:45	YES	19:15	
			03FEB2010	YES	8:30			
			04FEB2010	YES	8:30	YES	18:15	
			05FEB2010	YES	8:00	YES	18:00	
			06FEB2010	YES	9:15	YES	18:30	
			07FEB2010	YES	9:30	YES	19:00	
			08FEB2010	YES	7:30	YES	19:30	
			09FEB2010	YES	7:00	YES	18:00	
			10FEB2010	YES	9:30	YES	18:15	
			11FEB2010	YES	7:00	YES	18:00	
			12FEB2010	YES	7:30	YES	21:00	
			13FEB2010	YES	10:00	YES	20:30	
			14FEB2010	YES	9:30			
			15FEB2010	YES	8:00	YES	20:00	
			16FEB2010	YES	7:00	YES	18:30	
			17FEB2010	YES	8:30	YES	19:00	
			18FEB2010	YES	7:45	YES	19:30	
			19FEB2010	YES	8:00	YES	19:00	
			20FEB2010	YES	9:30	YES	19:00	
			21FEB2010	YES	10:00	YES	18:45	
			22FEB2010	YES	9:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	23FEB2010	YES	8:30	YES	18:45	
			24FEB2010	YES	7:00	YES	19:00	
			25FEB2010	YES	8:00	YES	18:30	
			26FEB2010	YES	8:30	YES	18:00	
			27FEB2010	YES	8:00	YES	19:00	
			28FEB2010	YES	9:00	YES	18:30	
			01MAR2010	YES	7:45	YES	18:15	
			02MAR2010	YES	8:00	YES	18:30	
			03MAR2010	YES	10:10			
			03MAR2010			YES	18:30	
			04MAR2010	YES	8:00	YES	19:30	
			05MAR2010	YES	8:00	YES	19:00	
			06MAR2010	YES	8:00	YES	20:00	
			07MAR2010	YES	9:00	YES	19:00	
			08MAR2010	YES	8:30	YES	18:15	
			09MAR2010	YES	8:00	YES	18:30	
			10MAR2010	YES	8:30	YES	18:45	
			11MAR2010	YES	8:00	YES		
			12MAR2010	YES	8:30	YES	18:45	
			13MAR2010	YES	9:00	YES	19:00	
			14MAR2010	YES	9:00	YES	19:00	
			15MAR2010	YES	8:30	YES	18:30	
			16MAR2010	YES	8:00	YES	18:45	
			17MAR2010	YES	7:45	YES		
			18MAR2010	YES	7:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	19MAR2010	YES	7:30	YES	19:15	
			20MAR2010	YES	7:45	YES	18:30	
			21MAR2010	YES	9:30	YES	19:45	Nach Tablette nicht mehr gegessen.
			22MAR2010	YES	8:30	YES	18:00	
			23MAR2010	YES	8:30	YES	17:45	
			24MAR2010	YES	7:30	YES	18:45	
			25MAR2010	YES	8:00	YES	19:00	
			26MAR2010	YES	8:15	YES	19:00	
			27MAR2010	YES	8:15	YES	18:30	
			28MAR2010	YES	9:30	YES	18:00	
			29MAR2010	YES	9:15	YES	17:45	
			30MAR2010	YES	8:45	YES	19:15	
			31MAR2010	YES	8:00	YES	19:00	
			01APR2010	YES	7:30	YES	18:45	
			02APR2010	YES	8:00	YES	18:30	
			03APR2010	YES	9:00	YES	19:00	
			04APR2010	YES	9:30	YES	19:45	
			05APR2010	YES	8:15	YES	18:45	
			06APR2010	YES	7:30	YES	19:00	
			07APR2010	YES	8:00	YES	18:30	Nach Tabletteneinnahme nicht mehr gegessen.
			08APR2010	YES	7:30	YES	18:30	
			09APR2010	YES	8:00	YES	18:30	
			10APR2010	YES	8:30	YES	18:00	Nach Tabletteneinnahme nicht mehr gegessen.
			11APR2010	YES	9:00	YES	17:45	
			12APR2010	YES	8:00	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	13APR2010	YES	7:30	YES	19:00	
			14APR2010	YES	8:30	YES	18:45	
			15APR2010	YES	8:00	YES	17:30	
			16APR2010	YES	7:30	YES	18:30	
			17APR2010	YES	9:00	YES	18:30	
			18APR2010	YES	9:00	YES	18:00	
			19APR2010	YES	8:00	YES	18:30	
			20APR2010	YES	7:00			
			20APR2010			YES	19:00	
			21APR2010	YES	7:30	YES	19:00	
			22APR2010	YES	8:30	YES	20:00	
			23APR2010	YES	8:00	YES	19:00	
			24APR2010	YES	9:30	YES	20:00	
			25APR2010	YES	9:15	YES	19:30	
			26APR2010	YES	8:00	YES	20:00	
			27APR2010	YES	7:30	YES	18:00	
			28APR2010	YES	8:30	YES	19:00	
			29APR2010	YES	8:00	YES	19:15	
			30APR2010	YES	7:30	YES	20:00	
			01MAY2010	YES	8:00	YES	19:00	
			02MAY2010	YES	9:00	YES	18:30	
			03MAY2010	YES	8:30	YES	19:30	
			04MAY2010	YES	7:30	YES	19:15	
			05MAY2010	YES	7:30	YES	19:45	
			06MAY2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	07MAY2010	YES	7:30	YES	19:00	
			08MAY2010	YES	9:00	YES	19:00	
			09MAY2010	YES	9:30	YES	19:30	
			10MAY2010	YES	8:00	YES	19:15	
			11MAY2010	YES	8:30	YES	20:00	
			12MAY2010	YES	8:15	YES	19:00	
			13MAY2010	YES	9:00	YES	18:45	
			14MAY2010	YES	8:00	YES	19:15	
			15MAY2010	YES	9:00	YES	18:30	
			16MAY2010	YES	9:00	YES	18:30	
			17MAY2010	YES	8:45	YES	18:30	
			18MAY2010	YES	8:00	YES	21:00	
			19MAY2010	YES	9:00	YES	19:15	
			20MAY2010	YES	8:00	YES	18:45	
			21MAY2010	YES	7:30	YES	19:30	
			22MAY2010	YES	8:45	YES	18:45	
			23MAY2010	YES	8:00	YES	19:00	
			24MAY2010	YES	8:15	YES	19:30	
			25MAY2010	YES	8:00	YES	18:30	
			26MAY2010	YES	8:45	YES	18:45	
			27MAY2010	YES	8:30	YES	18:00	
			28MAY2010	YES	9:00	YES	19:00	
			29MAY2010	YES	8:15	YES	18:00	
			30MAY2010	YES	8:00	YES	18:30	
			31MAY2010	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	01JUN2010	YES	9:00	YES	18:30	
			02JUN2010	YES	8:45	YES	18:00	
			03JUN2010	YES	9:15	YES	19:15	
			04JUN2010	YES	8:00	YES	19:00	
			05JUN2010	YES	9:15	YES	18:15	
			06JUN2010	YES	8:30	YES	18:45	
			07JUN2010	YES	9:00	YES	19:00	
			08JUN2010	YES	9:15	YES	19:30	
			09JUN2010	YES	7:30	YES	19:00	
			10JUN2010	YES	8:30	YES	18:45	
			11JUN2010	YES	8:00	YES	18:45	
			12JUN2010	YES	8:45	YES	19:00	
			13JUN2010	YES	8:00	YES	19:00	
			14JUN2010	YES	9:00	YES	18:45	
			15JUN2010	YES	8:30	YES	19:00	
			16JUN2010	YES	8:00	YES	19:00	
			17JUN2010	YES	8:45	YES	18:30	
			18JUN2010	YES	8:30	YES	19:00	
			19JUN2010	YES	8:30	YES	19:15	
			20JUN2010	YES	9:00	YES	19:00	
			21JUN2010	YES	8:30	YES	18:45	
			22JUN2010	YES	8:30	YES	18:45	
			23JUN2010	YES	8:00	YES	19:00	
			24JUN2010	YES	7:30	YES	19:00	
			25JUN2010	YES	8:15	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	26JUN2010	YES	8:30	YES	18:30	
			27JUN2010	YES	8:30	YES	18:00	
			28JUN2010	YES	8:30	YES	18:00	
			29JUN2010	YES	8:00	YES	18:30	
			30JUN2010	YES	8:30	YES	18:30	
			01JUL2010	YES	8:30	YES	18:30	
			02JUL2010	YES	8:00	YES	19:30	
			03JUL2010	YES	8:15	YES	18:00	
			04JUL2010	YES	8:00	YES	18:00	
			05JUL2010	YES	7:00			
			05JUL2010			YES	19:00	
			06JUL2010	YES	7:00	YES	17:30	
			07JUL2010	YES	6:30	YES	18:00	
			08JUL2010	YES	9:30	YES	18:00	
			09JUL2010	YES	9:15	YES	18:30	
			10JUL2010	YES	9:30	YES	18:00	
			11JUL2010	YES	9:30	YES	20:00	
			12JUL2010	YES	8:00	YES	18:30	
			13JUL2010	YES	8:45	YES	18:45	
			14JUL2010	YES	9:00	YES	19:10	
			15JUL2010	YES	8:30	YES	18:30	
			16JUL2010	YES	8:30	YES	18:30	
			17JUL2010	YES	8:45	YES	19:00	
			18JUL2010	YES	9:00	YES	18:45	
			19JUL2010	YES	9:15	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	20JUL2010	YES	8:45	YES	18:30	
			21JUL2010	YES	8:30	YES	19:00	
			22JUL2010	YES	8:15	YES	18:45	
			23JUL2010	YES	8:15	YES	18:30	
			24JUL2010	YES	8:00	YES	18:15	
			25JUL2010	YES	9:00	YES	18:45	
			26JUL2010	YES	9:00	YES	18:00	
			27JUL2010	YES	8:00	YES	18:45	Kopfweg
			28JUL2010	YES	8:15	YES	18:30	
			29JUL2010	YES	8:45	YES	18:00	
			30JUL2010	YES	9:00	YES	19:00	
			31JUL2010	YES	9:00	YES	19:15	
			01AUG2010	YES	9:15	YES	18:45	
			02AUG2010	YES	9:00	YES	19:00	
			03AUG2010	YES	8:45	YES	19:30	
			04AUG2010	YES	9:00	YES	18:45	
			05AUG2010	YES	9:00	YES	18:00	
			06AUG2010	YES	8:30	YES	18:00	
			07AUG2010	YES	6:00	YES	20:00	
			08AUG2010	YES	9:00	YES	18:30	
			09AUG2010	YES	8:00	YES	18:00	
			10AUG2010	YES	8:30	YES	19:00	Harnwegentzündung
			11AUG2010	YES	8:45	YES	19:00	
			12AUG2010	YES	9:00	YES	18:45	
			13AUG2010	YES	8:15	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	14AUG2010	YES	8:06	YES	19:00	Kopfschmerz
			15AUG2010	YES	9:00	YES	18:00	
			16AUG2010	YES	8:00	YES	18:30	
			17AUG2010	YES	8:00	YES	17:00	
			18AUG2010	YES	8:00	YES	19:00	
			19AUG2010	YES	8:45	YES	18:30	
			20AUG2010	YES	8:30	YES	18:30	
			21AUG2010	YES	9:00	YES	18:00	
			22AUG2010	YES	9:00	YES	18:00	Völlegefühl
			23AUG2010	YES	8:30	YES	19:00	
			24AUG2010	YES	8:00	YES	19:00	
			25AUG2010	YES	8:00	YES	18:45	
			26AUG2010	YES	8:30	YES	18:45	
			27AUG2010	YES	8:30	YES	19:00	
			29AUG2010	YES	8:30	YES	19:00	
			30AUG2010	YES	8:30	YES	19:00	
			31AUG2010	YES	8:15	YES	18:45	
			01SEP2010	YES	8:30	YES	18:45	
			02SEP2010	YES	8:30	YES	19:00	
			03SEP2010	YES	8:30	YES	18:45	
			04SEP2010	YES	8:45	YES	18:45	
			05SEP2010	YES	8:15	YES	18:30	
			06SEP2010	YES	8:00	YES	18:30	
			07SEP2010	YES	8:30	YES	19:00	
			08SEP2010	YES	9:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	09SEP2010	YES	8:00	YES	18:30	
			10SEP2010	YES	8:15	YES	18:30	
			11SEP2010	YES	8:45	YES	19:00	
			12SEP2010	YES	8:30	YES	19:30	
			13SEP2010	YES	9:00	YES	19:15	
			14SEP2010	YES	8:30	YES	19:15	
			15SEP2010	YES	8:00	YES	18:30	
			16SEP2010	YES	7:45	YES	18:00	
			17SEP2010	YES	8:30	YES	18:00	
			18SEP2010	YES	8:45	YES	19:00	
			19SEP2010	YES	9:30	YES	18:00	
			20SEP2010	YES	8:30	YES	18:00	
			21SEP2010	YES	8:00	YES	18:15	
			22SEP2010	YES	8:15	YES	19:00	
			23SEP2010	YES	8:30	YES	18:30	
			24SEP2010	YES	8:30	YES	18:30	
			25SEP2010	YES	8:15	YES	19:00	
			26SEP2010	YES	9:00	YES	18:00	
			27SEP2010	YES	8:45	YES	19:30	
			28SEP2010	YES	8:30	YES	18:30	
			29SEP2010	YES	8:30	YES	18:30	
			30SEP2010	YES	7:00			
			30SEP2010	YES		YES	18:45	
			01OCT2010	YES	8:00	YES	18:00	
			02OCT2010	YES	7:30	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	03OCT2010	YES	9:15	YES	19:00	
			04OCT2010	YES	8:30	YES	18:00	
			05OCT2010	YES	8:30	YES	18:15	
			06OCT2010	YES	8:45	YES	19:00	
			07OCT2010	YES	8:30	YES	18:00	
			08OCT2010	YES	7:15	YES	18:45	
			09OCT2010	YES	8:00	YES	18:00	
			10OCT2010	YES	9:00	YES	18:30	
			11OCT2010	YES	8:30	YES	18:30	
			12OCT2010	YES	7:45	YES	19:00	
			13OCT2010	YES	8:00	YES	18:00	
			14OCT2010	YES	8:15	YES	18:30	Kopfschmerzen
			15OCT2010	YES	8:45	YES	18:30	
			16OCT2010	YES	9:00	YES	17:00	
			17OCT2010	YES	9:00	YES	19:00	
			18OCT2010	YES	8:30	YES	18:45	
			19OCT2010	YES	7:45	YES	18:00	
			20OCT2010	YES	7:30	YES	19:00	
			21OCT2010	YES	8:30	YES	18:45	
			22OCT2010	YES	8:30	YES	18:30	
			23OCT2010	YES	8:30	YES	18:00	
			24OCT2010	YES	8:30	YES	18:45	
			25OCT2010	YES	8:30	YES	18:00	
			26OCT2010	YES	8:30	YES	18:45	
			27OCT2010	YES	7:45	YES	18:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	28OCT2010	YES	8:00	YES	18:30	
			29OCT2010	YES	8:15	YES	18:15	
			30OCT2010	YES	8:30	YES	18:00	
			31OCT2010	YES	8:30	YES	18:00	
			01NOV2010	YES	8:45	YES	19:00	
			02NOV2010	YES	8:30	YES	18:15	
			03NOV2010	YES	8:30	YES	18:00	
			04NOV2010	YES	8:00	YES	18:45	
			05NOV2010	YES	7:45	YES	18:30	
			06NOV2010	YES	8:15	YES	19:00	
			07NOV2010	YES	8:30	YES	18:45	
			08NOV2010	YES	8:30	YES	18:30	
			09NOV2010	YES	8:45	YES	18:30	
			10NOV2010	YES	8:45	YES	19:00	
			11NOV2010	YES	8:30	YES	18:30	
			12NOV2010	YES	8:30	YES	18:45	
			13NOV2010	YES	9:00	YES	19:00	
			14NOV2010	YES	8:30	YES	18:45	
			15NOV2010	YES	8:15	YES	18:30	
			16NOV2010	YES	8:30	YES	18:15	
			17NOV2010	YES	7:15	YES	18:30	
			18NOV2010	YES	8:00	YES	18:30	
			19NOV2010	YES	8:45	YES	18:30	
			20NOV2010	YES	8:30	YES	19:00	
			21NOV2010	YES	8:30	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	22NOV2010	YES	8:30	YES	18:45	
			23NOV2010	YES	8:15	YES	18:00	
			24NOV2010	YES	8:00	YES	19:00	
			25NOV2010	YES	8:45	YES	18:30	
			26NOV2010	YES	7:00	YES	18:45	
			27NOV2010	YES	8:30	YES	18:30	
			28NOV2010	YES	9:00	YES	18:00	
			29NOV2010	YES	8:30	YES	18:45	
			30NOV2010	YES	8:45	YES	18:30	
			01DEC2010	YES	8:30	YES	18:30	
			02DEC2010	YES	8:00	YES	18:30	
			03DEC2010	YES	7:30	YES	18:30	
			04DEC2010	YES	8:30	YES	19:00	
			05DEC2010	YES	8:30	YES	18:30	
			06DEC2010	YES	8:30	YES	18:30	Kopfschmerzen
			07DEC2010	YES	8:45	YES	19:00	
			08DEC2010	YES	8:15	YES	18:00	
			09DEC2010	YES	8:30	YES	18:30	
			10DEC2010	YES	8:30	YES	18:45	
			11DEC2010	YES	8:30	YES	18:15	
			12DEC2010	YES	8:30	YES	18:30	
			13DEC2010	YES	8:30	YES	19:00	
			14DEC2010	YES	7:00	YES	18:30	
			15DEC2010	YES	8:00	YES	18:00	
			16DEC2010	YES	8:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	17DEC2010	YES	8:15	YES	18:30	
			18DEC2010	YES	8:45	YES	19:00	
			19DEC2010	YES	9:00	YES	18:00	
			20DEC2010	YES	8:15	YES	18:00	
			21DEC2010	YES	8:00	YES	18:30	
			22DEC2010	YES	8:00	YES	18:30	
			23DEC2010	YES	8:45	YES	19:00	
			24DEC2010	YES	9:00	YES	18:00	
			25DEC2010	YES	8:45	YES	18:30	
			26DEC2010	YES	9:00	YES	18:45	
			27DEC2010	YES	8:15	YES	18:30	
			28DEC2010	YES	8:30	YES	18:30	
			29DEC2010	YES	8:00	YES	18:00	
			30DEC2010	YES	8:30	YES	18:30	
			31DEC2010	YES	9:00	YES	19:30	
			01JAN2011	YES	9:00	YES	18:00	
			02JAN2011	YES	9:00	YES	18:45	
			03JAN2011	YES	8:00	YES	18:30	
			04JAN2011	YES	8:15	YES	18:00	
			05JAN2011	YES	8:30	YES	18:00	
			06JAN2011	YES	8:30	YES	18:15	
			07JAN2011	YES	8:30	YES	18:00	
			08JAN2011	YES	8:00	YES	18:30	
			09JAN2011	YES	8:30	YES	18:30	
			10JAN2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	029	8	11JAN2011	YES	8:00	YES	18:30	
			12JAN2011	YES	8:30	YES	19:00	
			13JAN2011	YES	8:15	YES	18:30	
			14JAN2011	YES	8:30	YES	18:30	
			15JAN2011	YES	8:30	YES	18:45	
			16JAN2011	YES	8:30	YES	18:00	
			17JAN2011	YES	9:00	YES	18:30	
			18JAN2011	YES	8:30	YES	18:30	
			19JAN2011	YES	8:45	YES	18:15	
			20JAN2011	YES	8:15	YES	18:30	
			21JAN2011	YES	8:30	YES	18:30	
			22JAN2011	YES	8:30	YES	18:30	
			23JAN2011	YES	8:30	YES	18:15	
			24JAN2011	YES	8:30	YES	18:45	
			25JAN2011	YES	8:30	YES	18:30	
			26JAN2011	YES	8:30	YES	18:15	
			27JAN2011	YES	8:30	YES	18:30	
			28JAN2011	YES	8:30	YES	18:30	
			29JAN2011	YES	8:30	YES	18:45	
			30JAN2011	YES	8:30	YES	18:30	
			31JAN2011	YES	8:30	YES	18:30	
			01FEB2011	YES	7:00			
	031	8	20JAN2010	YES	8:10	YES	17:45	
			21JAN2010	YES	8:15	YES	18:00	

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16= Leipzig, 17= Hannover, 18= Nürnberg, 20= Graz, 21= Innsbruck, 22= Linz, 23= Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	20MAY2010			YES	17:30	
			21MAY2010	YES	8:30	YES	18:00	
			22MAY2010	YES	8:30	YES	17:30	
			23MAY2010	YES	7:30	YES	19:30	
			24MAY2010	YES	9:00	YES	18:00	
			25MAY2010	YES	8:30	YES	18:00	
			26MAY2010	YES	8:30	YES	18:00	
			27MAY2010	YES	9:30	YES	17:30	
			28MAY2010	YES	8:00	YES	18:00	
			29MAY2010	YES	9:00	YES	19:00	
			30MAY2010	YES	9:15	YES	18:30	
			31MAY2010	YES	8:00	YES	17:30	
			01JUN2010	YES	8:30	YES	17:45	
			02JUN2010	YES	8:20	YES	18:15	
			03JUN2010	YES	9:15	YES	19:00	
			04JUN2010	YES	8:00	YES	18:00	
			05JUN2010	YES	9:00	YES	18:00	
			06JUN2010	YES	9:10	YES	18:15	
			07JUN2010	YES	8:00	YES	17:45	
			08JUN2010	YES	8:15	YES	18:00	
			09JUN2010	YES	8:15	YES	17:45	
			10JUN2010	YES	8:00	YES	18:00	
			11JUN2010	YES	8:30	YES	18:15	
			12JUN2010	YES	8:00	YES	19:00	
			13JUN2010	YES	9:00	YES	18:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	14JUN2010	YES	8:15	YES	17:45	
			15JUN2010	YES	7:15			
			15JUN2010			YES	18:00	
			16JUN2010	YES	8:00	YES	17:30	
			17JUN2010	YES	8:15	YES	17:30	
			18JUN2010	YES	8:00	YES	17:45	
			19JUN2010	YES	9:00	YES	18:00	
			20JUN2010	YES	9:15	YES	18:30	
			21JUN2010	YES	8:00	YES	17:30	
			22JUN2010	YES	8:10	YES	17:45	
			23JUN2010	YES	8:00	YES	18:00	
			24JUN2010	YES	8:15	YES	18:00	
			25JUN2010	YES	8:00	YES	18:00	
			26JUN2010	YES	8:10	YES	17:30	
			27JUN2010	YES	9:30	YES	18:30	
			28JUN2010	YES	8:00	YES	17:15	
			29JUN2010	YES	8:15	YES	17:45	
			30JUN2010	YES	8:00	YES	18:00	
			01JUL2010	YES	8:30	YES	17:45	
			02JUL2010	YES	8:10	YES	18:00	
			03JUL2010	YES	9:00	YES	18:00	
			04JUL2010	YES	9:00	YES	18:30	
			05JUL2010	YES	9:00	YES	18:45	
			06JUL2010	YES	8:30	YES	18:15	
			07JUL2010	YES	9:00	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	08JUL2010	YES	9:30	YES	19:00	
			09JUL2010	YES	9:45	YES	19:15	
			10JUL2010	YES	9:15	YES	19:00	
			11JUL2010	YES	9:30	YES	19:45	
			12JUL2010	YES	9:15	YES	18:45	
			13JUL2010	YES	9:20	YES	19:00	
			14JUL2010	YES	9:10	YES	19:15	
			15JUL2010	YES	9:00	YES	18:15	
			16JUL2010	YES	9:10	YES	19:00	
			17JUL2010	YES	9:30	YES	18:00	
			18JUL2010	YES	10:30	YES	19:00	
			19JUL2010	YES	9:15	YES	18:30	
			20JUL2010	YES	9:00	YES	18:20	
			21JUL2010	YES	9:15	YES	18:00	
			22JUL2010	YES	9:00	YES	18:30	
			23JUL2010	YES	9:15	YES	18:20	
			24JUL2010	YES	9:00	YES	18:15	
			25JUL2010	YES	8:30	YES	18:00	
			26JUL2010	YES	8:00	YES	17:30	
			27JUL2010	YES	8:15	YES	17:45	
			28JUL2010	YES	8:00	YES	18:00	
			29JUL2010	YES	8:30	YES	18:15	
			30JUL2010	YES	8:10	YES	17:45	
			31JUL2010	YES	9:30	YES	18:00	
			01AUG2010	YES	9:15	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	02AUG2010	YES	8:00	YES	17:40	
			03AUG2010	YES	8:20	YES	18:05	
			04AUG2010	YES	7:45	YES	17:55	
			05AUG2010	YES	8:00	YES	18:00	
			06AUG2010	YES	7:55	YES	19:00	
			07AUG2010	YES	9:30	YES	18:30	
			08AUG2010	YES	10:00	YES	19:10	
			09AUG2010	YES	8:00	YES	17:20	
			10AUG2010	YES	8:15	YES	17:30	
			11AUG2010	YES	8:00	YES	18:00	
			12AUG2010	YES	7:15	YES	18:05	
			13AUG2010	YES	7:30	YES	17:55	
			14AUG2010	YES	9:00	YES	18:00	
			15AUG2010	YES	8:55	YES	18:15	
			16AUG2010	YES	8:00	YES	17:45	
			17AUG2010	YES	7:00			
			17AUG2010			YES	18:00	
			18AUG2010	YES	8:00	YES	17:30	
			19AUG2010	YES	7:45	YES	17:30	
			20AUG2010	YES	8:30	YES	17:45	
			21AUG2010	YES	8:45	YES	17:30	
			22AUG2010	YES	9:00	YES	17:45	
			23AUG2010	YES	8:00	YES	17:30	
			24AUG2010	YES	8:15	YES	17:20	
			25AUG2010	YES	8:00	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	26AUG2010	YES	8:10	YES	18:00	
			27AUG2010	YES	8:15	YES	18:10	
			28AUG2010	YES	9:00	YES	18:00	
			29AUG2010	YES	9:15	YES	18:30	
			30AUG2010	YES	8:00	YES	17:30	
			31AUG2010	YES	8:10	YES	17:45	
			01SEP2010	YES	8:15	YES	18:00	
			02SEP2010	YES	8:00	YES	17:10	
			03SEP2010	YES	8:15	YES	17:20	
			04SEP2010	YES	9:00	YES	18:15	
			05SEP2010	YES	9:00	YES	18:30	
			06SEP2010	YES	8:00	YES	17:45	
			07SEP2010	YES	8:15	YES	18:00	
			08SEP2010	YES	8:10	YES	17:40	
			09SEP2010	YES	8:10	YES	18:00	
			10SEP2010	YES	8:00	YES	17:50	
			11SEP2010	YES	8:30	YES	18:05	
			12SEP2010	YES	8:45	YES	18:00	
			13SEP2010	YES	8:00	YES	17:10	
			14SEP2010	YES	8:05	YES	17:45	
			15SEP2010	YES	8:15	YES	17:55	
			16SEP2010	YES	8:10	YES	18:00	
			17SEP2010	YES	8:00	YES	18:10	
			18SEP2010	YES	8:10	YES	18:00	
			19SEP2010	YES	8:15	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	20SEP2010	YES	8:00	YES	17:55	
			21SEP2010	YES	8:15	YES	18:00	
			22SEP2010	YES	8:20	YES	18:00	
			23SEP2010	YES	8:15	YES	18:00	
			24SEP2010	YES	8:20	YES	17:55	
			25SEP2010	YES	8:15	YES	17:45	
			26SEP2010		8:45	YES	18:15	
			27SEP2010	YES	8:10	YES	18:00	
			28SEP2010	YES	8:15	YES	17:45	
			29SEP2010	YES	8:05	YES	17:55	
			30SEP2010	YES	8:10	YES	17:45	
			01OCT2010	YES	8:10	YES	18:00	
			02OCT2010		8:20	YES	18:05	
			03OCT2010	YES	8:30	YES	18:10	
			04OCT2010	YES	8:00	YES	18:00	
			05OCT2010	YES	8:15	YES	17:45	
			06OCT2010	YES	8:05	YES	17:55	
			07OCT2010	YES	8:10	YES	18:00	
			08OCT2010	YES	8:10	YES	18:15	
			09OCT2010	YES	8:20	YES	18:20	
			10OCT2010	YES	9:00	YES	18:30	
			11OCT2010	YES	8:05	YES	17:50	
			12OCT2010	YES	8:10	YES	17:45	
			13OCT2010	YES	8:15	YES	17:45	
			14OCT2010	YES	8:20	YES	17:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	15OCT2010	YES	8:15	YES	17:50	
			16OCT2010	YES	8:25	YES	17:45	
			17OCT2010	YES	8:30	YES	18:10	
			18OCT2010	YES	8:15	YES	18:05	
			19OCT2010	YES	8:05	YES	17:45	
			20OCT2010	YES	8:20	YES	17:45	
			21OCT2010	YES	8:00	YES	17:45	
			22OCT2010	YES	8:05	YES	17:50	
			22OCT2010	YES	8:30	YES	18:00	
			23OCT2010	YES	8:00	YES	18:00	
			23OCT2010	YES	8:40	YES	18:15	
			24OCT2010	YES	8:15	YES	17:45	
			24OCT2010	YES	8:00	YES	17:45	
			25OCT2010	YES	8:00	YES	17:55	
			25OCT2010	YES	6:30			
			26OCT2010	YES	8:15	YES	18:30	
			27OCT2010	YES	8:00	YES	17:45	
			28OCT2010	YES	8:15	YES	17:55	
			29OCT2010	YES	8:10	YES	18:00	
			30OCT2010	YES	8:30	YES	18:00	
			31OCT2010	YES	8:20	YES	18:05	
			01NOV2010	YES	9:00	YES	17:45	
			02NOV2010	YES	8:00	YES	17:30	
			03NOV2010	YES	8:20	YES	18:00	
			04NOV2010	YES	8:10	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	05NOV2010	YES	8:20	YES	18:00	
			06NOV2010	YES	9:00	YES	18:30	
			07NOV2010	YES	8:45	YES	18:15	
			08NOV2010	YES	8:10	YES	18:00	
			09NOV2010	YES	6:00			
			09NOV2010			YES	18:00	
			10NOV2010	YES	8:30	YES	17:45	
			11NOV2010	YES	8:15	YES	17:50	
			12NOV2010	YES	8:30	YES	18:00	
			13NOV2010	YES	8:45	YES	18:15	
			14NOV2010	YES	9:00	YES	19:00	
			15NOV2010	YES	8:00	YES	17:55	
			16NOV2010	YES	8:10	YES	18:00	
			17NOV2010	YES	8:00	YES	17:45	
			18NOV2010	YES	7:45	YES	18:00	
			19NOV2010	YES	8:00	YES	17:30	
			20NOV2010	YES	9:00	YES	17:30	
			21NOV2010	YES	8:00	YES	17:45	
			22NOV2010	YES	8:15	YES	17:20	
			23NOV2010	YES	8:20	YES	18:00	
			24NOV2010	YES	8:00	YES	17:45	
			25NOV2010	YES	8:10	YES	17:55	
			26NOV2010	YES	8:00	YES	18:00	
			27NOV2010	YES	9:00	YES	18:15	
			28NOV2010	YES	9:00	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	29NOV2010	YES	7:45	YES	17:30	
			30NOV2010	YES	8:00	YES	17:45	
			01DEC2010	YES	7:50	YES	17:30	
			02DEC2010	YES	8:00	YES	17:45	
			03DEC2010	YES	7:45	YES	18:00	
			04DEC2010	YES	9:00	YES	19:15	
			05DEC2010	YES	9:10	YES	18:00	
			06DEC2010	YES	7:00	YES	17:30	
			07DEC2010	YES	7:15	YES	17:40	
			08DEC2010	YES	8:00	YES	17:15	
			09DEC2010	YES	8:15	YES	17:55	
			10DEC2010	YES	7:50	YES	18:00	
			11DEC2010	YES	9:10	YES	18:00	
			12DEC2010	YES	9:00	YES	18:10	
			13DEC2010	YES	7:50	YES	17:30	
			14DEC2010	YES	8:00	YES	17:30	
			15DEC2010	YES	8:10	YES	17:30	
			16DEC2010	YES	8:00	YES	18:15	
			17DEC2010	YES	8:10	YES	18:00	
			18DEC2010	YES	8:50	YES	19:00	
			19DEC2010	YES	9:00	YES	18:00	
			20DEC2010	YES	8:00	YES	17:15	
			21DEC2010	YES	8:10	YES	17:45	
			22DEC2010	YES	8:05	YES	18:00	
			23DEC2010	YES	8:15	YES	17:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	24DEC2010	YES	9:00	YES	19:30	
			25DEC2010	YES	9:15	YES	18:45	
			26DEC2010	YES	9:00	YES	19:00	
			27DEC2010	YES	9:30	YES	18:15	
			28DEC2010	YES	8:15	YES	17:15	
			29DEC2010	YES	8:00	YES	17:15	
			30DEC2010	YES	8:10	YES	17:55	
			31DEC2010	YES	9:00	YES	18:00	
			01JAN2011	YES	9:05	YES	18:10	
			02JAN2011	YES	9:10	YES	18:45	
			03JAN2011	YES	8:00	YES	17:45	
			04JAN2011	YES	8:05	YES	18:00	
			05JAN2011	YES	8:00	YES	17:40	
			06JAN2011	YES	8:05	YES	17:45	
			07JAN2011	YES	7:45	YES	17:20	
			08JAN2011	YES	8:30	YES	17:25	
			09JAN2011	YES	9:00	YES	18:10	
			10JAN2011	YES	8:00	YES	17:40	
			11JAN2011	YES	6:30	YES	18:00	
			12JAN2011	YES	8:00	YES	17:20	
			13JAN2011	YES	8:30	YES	18:00	
			14JAN2011	YES	8:00	YES	17:50	
			15JAN2011	YES	8:30	YES	17:45	
			16JAN2011	YES	8:35	YES	18:00	
			17JAN2011	YES	8:00	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	18JAN2011	YES	8:15	YES	18:00	
			19JAN2011	YES	8:00	YES	17:55	
			25JAN2011			YES	18:00	
			26JAN2011	YES	8:30	YES	17:30	
			27JAN2011	YES	8:15	YES	17:45	
			28JAN2011	YES	8:00	YES	18:00	
			29JAN2011	YES	9:00	YES	18:00	
			30JAN2011	YES	9:00	YES	18:10	
			31JAN2011	YES	8:00	YES	17:45	
			01FEB2011	YES	8:15	YES	17:50	
			02FEB2011	YES	8:00	YES	17:45	
			03FEB2011	YES	8:10	YES	18:00	
			04FEB2011	YES	8:00	YES	18:00	
			05FEB2011	YES	8:30	YES	17:50	
			06FEB2011	YES	9:00	YES	18:00	
			07FEB2011	YES	8:15	YES	17:45	
			08FEB2011	YES	8:10	YES	17:45	
			09FEB2011	YES	8:15	YES	17:30	
			10FEB2011	YES	8:20	YES	17:30	
			11FEB2011	YES	8:10	YES	18:00	
			12FEB2011	YES	9:00	YES	18:00	
			13FEB2011	YES	8:45	YES	18:10	
			14FEB2011	YES	8:10	YES	17:45	
			15FEB2011	YES	8:20	YES	17:50	
			16FEB2011	YES	8:15	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	17FEB2011	YES	8:20	YES	18:00	
			18FEB2011	YES	8:15	YES	18:00	
			19FEB2011	YES	8:30	YES	18:00	
			20FEB2011	YES	8:45	YES	18:15	
			21FEB2011	YES	8:00	YES	17:20	
			22FEB2011	YES	8:10	YES	17:45	
			23FEB2011	YES	8:20	YES	18:00	
			24FEB2011	YES	8:15	YES	18:10	
			25FEB2011	YES	8:00	YES	17:30	
			26FEB2011	YES	9:00	YES	18:30	
			27FEB2011	YES	8:45	YES	18:00	
			28FEB2011	YES	8:15	YES	17:30	
			01MAR2011	YES	8:10	YES	17:15	
			02MAR2011	YES	8:10	YES	18:00	
			03MAR2011	YES	8:00	YES	17:30	
			04MAR2011	YES	8:10	YES	17:45	
			05MAR2011	YES	8:15	YES	17:30	
			06MAR2011	YES	8:20	YES	17:45	
			07MAR2011	YES	8:10	YES	17:30	
			08MAR2011	YES	8:45	YES	17:45	
			09MAR2011	YES	8:10	YES	17:30	
			10MAR2011	YES	8:15	YES	17:45	
			11MAR2011	YES	8:10	YES	17:50	
			12MAR2011	YES	8:30	YES	18:00	
			13MAR2011	YES	8:45	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	14MAR2011	YES	8:10	YES	17:20	
			15MAR2011	YES	8:00	YES	18:00	
			16MAR2011	YES	7:20	YES	18:00	
			17MAR2011	YES	7:30	YES	18:00	
			18MAR2011	YES	7:20	YES	18:00	
			19MAR2011	YES	8:30	YES	18:10	
			20MAR2011	YES	8:45	YES	18:10	
			21MAR2011	YES	7:20	YES	18:15	
			22MAR2011	YES	7:20	YES	18:10	
			23MAR2011	YES	7:15	YES	18:00	
			24MAR2011	YES	7:20	YES	18:10	
			25MAR2011	YES	7:20	YES	18:05	
			26MAR2011	YES	8:45	YES	18:20	
			27MAR2011	YES	8:30	YES	18:00	
			28MAR2011	YES	7:20	YES	18:05	
			29MAR2011	YES	7:25	YES	18:00	
			30MAR2011	YES	7:20	YES	18:10	
			31MAR2011	YES	7:20	YES	18:05	
			01APR2011	YES	7:25	YES	18:05	
			02APR2011	YES	8:45	YES	18:30	
			03APR2011	YES	9:00	YES	18:45	
			04APR2011	YES	7:20	YES	18:00	
			05APR2011	YES	7:20	YES	18:05	
			06APR2011	YES	7:20	YES	18:10	
			07APR2011	YES	7:25	YES	18:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	08APR2011	YES	7:20	YES	18:00	
			09APR2011	YES	8:40	YES	17:30	
			10APR2011	YES	8:45	YES	18:20	
			11APR2011	YES	7:20	YES	18:05	
			12APR2011	YES	7:25	YES	18:10	
			13APR2011	YES	7:20	YES	18:00	
			14APR2011	YES	7:20	YES	18:00	
			15APR2011	YES	7:20	YES	18:05	
			16APR2011	YES	8:30	YES	19:00	
			17APR2011	YES	9:00	YES	18:45	
			18APR2011	YES	7:20	YES	18:05	
			19APR2011	YES	7:20	YES	18:10	
			20APR2011	YES	7:20	YES	18:00	
			21APR2011	YES	7:25	YES	18:10	
			22APR2011	YES	7:45	YES	18:00	
			23APR2011	YES	8:00	YES	18:00	
			24APR2011	YES	8:30	YES	18:30	
			25APR2011	YES	9:00	YES	18:15	
			26APR2011	YES	7:20	YES	18:00	
			27APR2011	YES	7:20	YES	18:05	
			28APR2011	YES	7:20	YES	18:00	
			29APR2011	YES	7:20	YES	18:10	
			30APR2011	YES	8:45	YES	17:30	
			01MAY2011	YES	8:30	YES	18:00	
			02MAY2011	YES	7:20	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	031	8	03MAY2011	YES	7:20	YES	18:00	
			04MAY2011	YES	7:20	YES	18:10	
			05MAY2011	YES	7:20	YES	18:15	
			06MAY2011	YES	7:25	YES	18:10	
			07MAY2011	YES	8:30	YES	18:30	
			08MAY2011	YES	8:30	YES	18:15	
			09MAY2011	YES	7:20	YES	18:05	
			10MAY2011	YES	7:25	YES	18:05	
			11MAY2011	YES	7:20	YES	18:10	
			12MAY2011	YES	7:20	YES	18:00	
			13MAY2011	YES	7:20	YES	18:10	
			14MAY2011	YES	8:30	YES	18:30	
			15MAY2011	YES	8:45	YES	19:00	
			16MAY2011	YES	7:20	YES	18:10	
			17MAY2011	YES	7:00			
	034	9	16APR1940	YES	7:00	YES	18:00	
			19MAR2010	YES	6:30	YES	17:30	
			20MAR2010	YES	7:00	YES	18:00	
			21MAR2010	YES	7:00	NO		
			22MAR2010	YES	7:00	YES	18:00	
			23MAR2010	YES	6:30	NO		vergessen
			24MAR2010	YES	7:00	YES	17:30	
			25MAR2010	YES	7:30	YES	17:30	
			26MAR2010	YES	8:00	YES	18:00	unwohl schon beim aufstehen

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	27MAR2010	YES	10:00	YES	18:00	
			28MAR2010	YES	7:00	YES	18:00	
			29MAR2010	YES	6:30	YES	18:00	
			30MAR2010	YES	6:30	YES	18:00	
			31MAR2010	YES	6:30	YES	20:00	
			01APR2010	YES	7:10	YES	18:00	
			02APR2010	YES	7:20	YES	17:30	
			03APR2010	YES	7:30	NO		vergessen
			04APR2010	YES	7:00	YES	17:00	
			05APR2010	YES	7:45	YES	18:30	
			06APR2010	YES	7:00	YES	18:00	
			07APR2010	YES	7:00	YES	18:00	
			08APR2010	YES	7:00	YES	20:30	nach dem Abendbrot?
			09APR2010	YES	6:45	YES	18:00	
			10APR2010	YES	8:00	YES	20:30	
			11APR2010	YES	8:00	YES	17:45	
			12APR2010	YES	7:00	YES	18:20	
			13APR2010	YES	7:00			
			13APR2010		7:00	YES	18:00	
			14APR2010	YES	7:00	YES	18:00	
			15APR2010	YES	7:00	YES	18:00	
			17APR2010	YES	8:00	YES	20:00	
			18APR2010	YES	8:00	YES	19:00	
			19APR2010	YES	7:00	YES	18:00	
			20APR2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	21APR2010	YES	7:00	YES	18:00	
			22APR2010	YES	7:00	YES	18:00	
			23APR2010	YES	7:00	YES	18:00	
			24APR2010	YES	7:00	YES	20:00	
			25APR2010	YES	7:20	YES	19:00	
			26APR2010	YES	7:00	YES	19:00	
			27APR2010	YES	7:00	YES	19:00	
			28APR2010	YES	7:00	YES	19:00	
			29APR2010	YES	7:30	YES	18:00	Unwohl
			30APR2010	YES	7:00	YES	18:00	
			01MAY2010	YES	7:30	YES	20:00	
			02MAY2010	YES	7:30	YES	18:00	
			03MAY2010	YES	7:00	YES	18:00	
			04MAY2010	YES	7:00	YES	18:00	
			05MAY2010	YES	7:00	YES	18:00	
			06MAY2010	YES	7:30	YES	20:00	
			07MAY2010	YES	7:00	YES	18:00	
			08MAY2010	YES	7:00	YES	18:00	
			09MAY2010	YES	8:00	YES	20:00	
			10MAY2010	YES	8:00	YES	18:00	
			11MAY2010	YES	7:00	YES	18:00	
			12MAY2010	YES	7:00	YES	18:00	
			13MAY2010	YES	7:30	YES	18:00	
			14MAY2010	YES	7:30	YES	18:00	
			15MAY2010	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	16MAY2010	YES	7:30	YES	19:00	
			17MAY2010	YES	7:00	YES	17:30	
			18MAY2010	YES	7:00	YES	17:30	
			19MAY2010	YES	7:00	YES	18:00	
			20MAY2010	YES	7:00	YES	18:00	
			21MAY2010	YES	7:00	YES	18:00	
			22MAY2010	YES	7:30	YES	20:00	
			23MAY2010	YES	8:00	YES	17:30	
			24MAY2010	YES	7:00	YES	18:00	
			25MAY2010	YES	7:00	YES	18:00	
			26MAY2010	YES	7:00	YES	18:00	
			27MAY2010	YES	7:00	YES	17:30	
			28MAY2010	YES	7:00	YES	18:30	
			29MAY2010	YES	7:00	YES	20:00	
			30MAY2010	YES	8:00	YES	20:00	
			31MAY2010	YES	7:00	YES	18:00	
			01JUN2010	YES	7:30	YES	18:00	
			02JUN2010	YES	7:00	YES	18:00	
			03JUN2010	YES	7:00	YES	18:00	
			04JUN2010	YES	7:00	YES	18:00	
			05JUN2010	YES	7:30	YES	20:00	
			06JUN2010	YES	8:00	YES	18:00	
			07JUN2010	YES	7:00	YES	18:00	
			08JUN2010	YES	7:15			
			09JUN2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	10JUN2010	YES	7:30	YES	20:00	
			11JUN2010	YES	7:00	YES	19:00	
			12JUN2010	YES	7:30	YES	19:00	
			13JUN2010	YES	7:30	YES	19:00	
			14JUN2010	YES	7:00	YES	19:00	
			15JUN2010	YES	7:30	YES	18:00	
			16JUN2010	YES	7:00	YES	20:00	
			17JUN2010	YES	7:00	YES	20:00	
			18JUN2010	YES	7:00	YES	19:00	
			19JUN2010	YES	7:00	YES	18:00	
			20JUN2010	YES	8:00	YES	18:00	
			21JUN2010	YES	7:00	YES	18:30	
			22JUN2010	YES	7:00	YES	19:00	
			23JUN2010	YES	7:00	YES	17:30	
			24JUN2010	YES	7:00	YES	17:30	
			25JUN2010	YES	7:00	YES	18:00	
			26JUN2010	YES	7:30	YES	19:00	
			27JUN2010	YES	8:00	YES	18:00	
			28JUN2010	YES	7:00	YES	18:30	
			29JUN2010	YES	7:00	YES	18:00	
			30JUN2010	YES	7:00	YES	18:00	
			01JUL2010	YES	7:00	YES	19:00	
			02JUL2010	YES	7:00	YES	17:30	
			03JUL2010	YES	8:00	YES	18:15	
			04JUL2010	YES	7:15	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	05JUL2010	YES	7:00	YES	18:00	
			06JUL2010	YES	7:00	YES	18:30	
			07JUL2010	YES	7:00	YES	18:30	
			08JUL2010	YES	7:00	YES	18:30	
			09JUL2010	YES	7:00	YES	18:30	
			10JUL2010	YES	7:00	YES	23:00	
			11JUL2010	YES	8:00	YES	19:00	
			12JUL2010	YES	7:00	YES	18:00	
			13JUL2010	YES	7:00	YES	18:00	
			14JUL2010	YES	7:00	YES	18:00	
			15JUL2010	YES	7:00	YES	21:00	
			16JUL2010	YES	7:00	YES	18:00	
			17JUL2010	YES	7:00	YES	18:30	
			18JUL2010	YES	8:00	YES	18:30	
			19JUL2010	YES	7:00	YES	18:00	
			20JUL2010	YES	7:00	YES	18:00	
			21JUL2010	YES	7:00	YES	18:00	
			22JUL2010	YES	7:00	YES	18:30	
			23JUL2010	YES	8:00	YES	18:30	
			24JUL2010	YES	8:00	YES	19:00	
			25JUL2010	YES	7:00	YES	18:00	
			26JUL2010	YES	7:00	YES	18:00	
			28JUL2010	YES	7:00	YES	19:00	
			29JUL2010	YES	7:00	YES	18:00	
			30JUL2010	YES	7:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	31JUL2010	YES	7:00	YES	18:00	
			01AUG2010	YES	9:00	YES	20:00	
			02AUG2010	YES	7:00	YES	18:00	
			03AUG2010	YES	7:00	YES	18:00	
			04AUG2010	YES	7:00	YES	18:00	
			05AUG2010	YES	7:00	YES	18:00	
			06AUG2010	YES	7:00	YES	18:00	
			07AUG2010	YES	8:00	YES	19:00	
			08AUG2010	YES	9:00	YES	19:00	
			09AUG2010	YES	7:00	YES	18:00	
			10AUG2010	YES	7:00	YES	18:00	
			11AUG2010	YES	7:00	YES	19:00	
			12AUG2010	YES	7:00	YES	19:00	
			13AUG2010	YES	7:00	YES	19:00	
			14AUG2010	YES	7:00	YES	19:00	
			15AUG2010	YES	8:00	YES	18:00	
			16AUG2010	YES	7:00	YES	18:30	
			17AUG2010	YES	7:00	YES	18:30	
			18AUG2010	YES	7:00	YES	20:00	
			19AUG2010	YES	7:00	YES	18:00	
			20AUG2010	YES	7:00	YES	18:00	
			21AUG2010	YES	8:00	YES	19:00	
			22AUG2010	YES	8:00	YES	19:00	
			23AUG2010	YES	7:00	YES	19:00	
			24AUG2010	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	25AUG2010	YES	7:00	YES	18:00	
			26AUG2010	YES	8:00	YES	18:00	
			27AUG2010	YES	7:00	YES	19:00	
			28AUG2010	YES	7:00	YES	19:00	
			29AUG2010	YES	8:00	YES	18:00	
			30AUG2010	YES	7:30	YES	17:30	
			31AUG2010	YES	7:30	YES	17:30	
			01SEP2010	YES	7:30	YES	17:30	
			02SEP2010	YES	7:30	YES	17:30	
			03SEP2010	YES	7:30	YES	17:30	
			04SEP2010	YES	7:30	YES	17:30	
			05SEP2010	YES	7:30	YES	17:00	
			06SEP2010	YES	7:00	YES	18:00	
			07SEP2010	YES	7:00	YES	18:00	
			08SEP2010	YES	7:00			
			08SEP2010	YES	7:00	YES	18:00	
			09SEP2010	YES	7:30	YES	18:00	
			10SEP2010	YES	7:00	YES	19:00	
			11SEP2010	YES	8:00	YES	18:00	
			12SEP2010	YES	8:00	YES	18:30	
			13SEP2010	YES	7:00	YES	18:00	
			14SEP2010	YES	8:00	YES	18:00	
			15SEP2010	YES	7:00	YES	19:00	
			16SEP2010	YES	8:00	YES	18:00	
			17SEP2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	18SEP2010	YES	7:30	YES	18:00	
			19SEP2010	YES	8:00	YES	19:00	
			20SEP2010	YES	7:00	YES	18:30	
			21SEP2010	YES	9:00	YES	19:00	
			22SEP2010	YES	7:00	YES	19:00	
			23SEP2010	YES	8:00	YES	19:00	
			24SEP2010	YES	7:00	YES	18:00	
			25SEP2010	YES	8:00	YES	18:30	
			26SEP2010	YES	8:30	YES	17:30	
			27SEP2010	YES	7:00	YES	18:00	
			28SEP2010	YES	9:00	YES	18:00	
			29SEP2010	YES	7:00	YES	18:00	
			30SEP2010	YES	7:30	YES	18:00	
			01OCT2010	YES	7:00	YES	18:00	
			02OCT2010	YES	8:00	YES	18:00	
			03OCT2010	YES	9:00	YES	19:00	
			04OCT2010	YES	7:00	YES	18:00	
			05OCT2010	YES	9:00	YES	18:00	
			06OCT2010	YES	7:00	YES	18:00	
			07OCT2010	YES	7:30	YES	18:00	
			08OCT2010	YES	7:00	YES	18:00	
			09OCT2010	YES	8:00	YES	19:00	
			10OCT2010	YES	8:00	YES	18:30	
			11OCT2010	YES	7:00	YES	18:00	
			12OCT2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	13OCT2010	YES	7:00	YES	18:00	
			14OCT2010	YES	8:00	YES	18:00	
			15OCT2010	YES	7:00	YES	18:00	
			16OCT2010	YES	8:00	YES	19:00	
			17OCT2010	YES	8:30	YES	18:00	
			18OCT2010	YES	7:00	YES	18:00	
			19OCT2010	YES	8:00	YES	18:00	
			20OCT2010	YES	7:00	YES	18:30	
			21OCT2010	YES	8:00	YES	18:00	
			22OCT2010	YES	7:00	YES	18:00	
			23OCT2010	YES	8:00	YES	19:00	
			24OCT2010	YES	9:00	YES	19:00	
			25OCT2010	YES	7:00	YES	18:00	
			26OCT2010	YES	8:00	YES	18:30	
			27OCT2010	YES	9:00	YES	18:00	
			28OCT2010	YES	8:30	YES	18:00	
			29OCT2010	YES	7:00	YES	18:00	
			30OCT2010	YES	8:00	YES	18:00	
			31OCT2010	YES	8:30	YES	18:00	
			01NOV2010	YES	7:00	YES	18:00	
			02NOV2010	YES	8:30	YES	18:00	
			03NOV2010	YES	7:00	YES	18:00	
			04NOV2010	YES	7:00	YES	18:00	
			05NOV2010	YES	7:00	YES	18:00	
			06NOV2010	YES	8:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	07NOV2010	YES	8:00	YES	18:00	
			08NOV2010	YES	7:00	YES	18:00	
			09NOV2010	YES	8:00	YES	18:00	
			10NOV2010	YES	7:00	YES	18:00	
			11NOV2010	YES	8:00	YES	18:00	
			12NOV2010	YES	7:00	YES	18:00	
			13NOV2010	YES	9:00	YES	18:00	
			14NOV2010	YES	8:30	YES	19:00	
			15NOV2010	YES	7:00	YES	18:00	
			16NOV2010	YES	8:00	YES	18:00	
			17NOV2010	YES	7:00	YES	18:00	
			18NOV2010	YES	8:00	YES	18:00	
			19NOV2010	YES	7:00	YES	19:00	
			20NOV2010	YES	8:00	YES	20:00	
			21NOV2010	YES	8:00	YES	19:00	
			22NOV2010	YES	7:00	YES	18:00	
			23NOV2010	YES	7:00	YES	18:00	
			24NOV2010	YES	7:00	YES	18:00	
			25NOV2010	YES	7:00	YES	18:00	
			26NOV2010	YES	7:00	YES	18:00	
			27NOV2010	YES	8:00	YES	18:00	
			28NOV2010	YES	8:30	YES	18:00	
			29NOV2010	YES	7:00	YES	18:00	
			30NOV2010	YES	7:00			
			30NOV2010			YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	01DEC2010	YES	7:00	YES	18:00	
			02DEC2010	YES	7:00	YES	18:00	
			03DEC2010	YES	8:00	YES	18:00	
			04DEC2010	YES	9:00	YES	18:00	
			05DEC2010	YES	9:00	YES	18:00	
			06DEC2010	YES	7:00	YES	18:00	
			07DEC2010	YES	8:00	YES	18:00	
			08DEC2010	YES	7:00	YES	18:00	
			09DEC2010	YES	8:00	YES	17:30	
			10DEC2010	YES	7:00	YES	18:00	
			11DEC2010	YES	8:00	YES	18:00	
			12DEC2010	YES	8:30	YES	18:00	
			13DEC2010	YES	7:00	YES	18:00	
			14DEC2010	YES	8:00	YES	18:00	
			15DEC2010	YES	7:00	YES	18:00	
			16DEC2010	YES	8:00	YES	18:00	
			17DEC2010	YES	8:00	YES	17:30	
			18DEC2010	YES	9:30	YES	20:30	
			19DEC2010	YES	9:00	YES	18:00	
			20DEC2010	YES	7:00	YES	18:00	
			21DEC2010	YES	8:00	YES	18:00	
			22DEC2010	YES	7:00	YES	18:00	
			23DEC2010	YES	9:00	YES	18:00	
			24DEC2010	YES	9:00	YES	22:00	
			25DEC2010	YES	9:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	26DEC2010	YES	8:30	YES	19:00	
			27DEC2010	YES	7:00	YES	18:00	
			28DEC2010	YES	8:30	YES	18:00	
			29DEC2010	YES	7:00	YES	18:00	
			30DEC2010	YES	8:30	YES	17:30	
			31DEC2010	YES	9:00	YES	18:00	
			01JAN2011	YES	9:00	YES	18:30	
			02JAN2011	YES	8:30	YES	18:00	
			03JAN2011	YES	7:00	YES	19:00	
			04JAN2011	YES	7:00	YES	18:00	
			05JAN2011	YES	7:00	YES	18:00	
			06JAN2011	YES	8:00	YES	18:00	
			07JAN2011	YES	7:00	YES	18:00	
			08JAN2011	YES	9:00	YES	18:00	
			09JAN2011	YES	9:00	YES	18:00	
			10JAN2011	YES	7:00	YES	18:00	
			11JAN2011	YES	8:30	YES	17:30	
			12JAN2011	YES	7:00	YES	17:30	
			13JAN2011	YES	8:30	YES	18:00	
			14JAN2011	YES	7:00	YES	18:00	
			15JAN2011	YES	8:30	YES	18:00	
			16JAN2011	YES	9:00	YES	18:00	
			17JAN2011	YES	7:15	YES	18:25	
			18JAN2011	YES	7:00	YES	20:00	
			19JAN2011	YES	7:20	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	20JAN2011	YES	7:00	YES	18:40	
			21JAN2011	YES	7:20	YES	18:30	
			22JAN2011	YES	9:30	YES	18:00	
			23JAN2011	YES	8:30	YES	18:00	
			24JAN2011	YES	7:15	YES	19:30	
			25JAN2011	YES	7:00	YES	18:30	
			26JAN2011	YES	7:15	YES	19:45	
			27JAN2011	YES	7:15	YES	18:45	
			28JAN2011	YES	7:30	YES	18:30	
			29JAN2011	YES	7:45	YES	19:00	
			30JAN2011	YES	8:00	YES	19:00	
			31JAN2011	YES	7:20	YES	18:30	
			01FEB2011	YES	7:00	YES	18:30	
			02FEB2011	YES	7:15	YES	18:00	
			03FEB2011	YES	7:25	YES	18:00	
			04FEB2011	YES	7:20	YES	18:30	
			05FEB2011	YES	8:30	YES	18:10	
			06FEB2011	YES	7:10	YES	18:30	
			07FEB2011	YES	7:00	YES	19:00	
			08FEB2011	YES	7:10	YES	18:20	
			09FEB2011	YES	7:00	YES	18:00	
			10FEB2011	YES	7:15	YES	18:30	
			11FEB2011	YES	8:30	YES	19:00	
			12FEB2011	YES	8:00	YES	19:10	
			13FEB2011	YES	8:10	YES	19:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	14FEB2011	YES	7:20	YES	19:00	
			15FEB2011	YES	7:00	YES	18:30	
			16FEB2011	YES	6:45	YES	18:30	
			17FEB2011	YES	6:30	YES	18:30	
			18FEB2011	YES	7:00	YES	18:30	
			19FEB2011	YES	8:00	YES	18:30	
			20FEB2011	YES	8:30	YES	17:30	
			21FEB2011	YES	7:00	YES	17:30	
			22FEB2011	YES	7:00	YES	18:00	
			23FEB2011	YES	7:00	YES	17:30	
			24FEB2011	YES	7:00	YES	17:30	
			25FEB2011	YES	7:00	YES	17:30	
			26FEB2011	YES	8:00	YES	17:30	
			27FEB2011	YES	8:30	YES	17:30	
			28FEB2011	YES	7:00	YES	18:00	
			01MAR2011	YES	7:30	YES	17:30	
			02MAR2011	YES	7:30	YES	17:30	
			03MAR2011	YES	7:30	YES	17:30	
			04MAR2011	YES	7:30	YES	17:30	
			05MAR2011	YES	8:00	YES	17:30	
			06MAR2011	YES	8:30	YES	17:30	
			07MAR2011	YES	7:00	YES	17:30	
			08MAR2011	YES	7:00	YES	17:30	
			09MAR2011	YES	7:15	YES	17:30	
			10MAR2011	YES	7:15	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	034	9	11MAR2011	YES	7:15	YES	17:30	
			12MAR2011	YES	8:00	YES	17:30	
			13MAR2011	YES	8:00	YES	17:30	
			14MAR2011	YES	7:15	YES	17:30	
			15MAR2011	YES	7:00	YES		08:30 Uni
	041	12	10OCT2009	YES	6:45	YES	17:30	
			11OCT2009	YES	7:00	YES	17:45	
			12OCT2009	YES	7:00	YES	17:30	
			13OCT2009	YES	7:00	YES	18:00	
			14OCT2009	YES	6:45	YES	17:30	
			15OCT2009	YES	6:45	YES	17:30	
			16OCT2009	YES	6:45	YES	17:45	
			17OCT2009	YES	7:00	YES	18:45	
			18OCT2009		7:00			
			19OCT2009	YES	6:45	YES	18:00	
			20OCT2009	YES	6:45	YES	17:30	
			21OCT2009	YES	6:45	YES	17:30	
			22OCT2009	YES	6:45	YES	17:45	
			23OCT2009	YES	6:45	YES	17:30	
			24OCT2009	YES	6:45	YES	17:30	
			25OCT2009	YES	7:00	YES	17:30	
			26OCT2009	YES	6:45	YES	17:30	
			27OCT2009	YES	6:45	YES	17:30	
			28OCT2009	YES	6:45	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	29OCT2009	YES	6:45	YES	17:30	
			30OCT2009	YES	6:45	YES	17:30	
			31OCT2009	YES	6:45	YES	17:30	
			01NOV2009	YES	7:00	YES	17:30	
			02NOV2009	YES	6:45	YES	17:30	
			03NOV2009	YES	6:45	YES	17:30	
			04NOV2009	YES	7:00	YES	17:30	
			05NOV2009	YES	6:45	YES	17:30	
			06NOV2009	YES	6:45	YES	17:30	
			07NOV2009	YES	6:45	YES	17:30	
			08NOV2009	YES	7:00	YES	17:30	
			09NOV2009		6:45			
			09NOV2009			YES	17:30	
			10NOV2009	YES	6:45	YES	17:30	
			11NOV2009	YES	6:45	YES	17:30	
			12NOV2009	YES	6:45	YES	18:00	
			13NOV2009	YES	6:45	YES	17:45	
			14NOV2009	YES	6:45	YES	17:30	
			15NOV2009	YES	6:45	YES	17:30	
			16NOV2009	YES	6:45	YES	17:30	
			17NOV2009	YES	6:45	YES	17:45	
			18NOV2009	YES	6:45	YES	18:00	3x täglich 40 Novaminsulfon Tropfen
			19NOV2009	YES	6:45	YES	17:30	3x täglich 40 Novaminsulfon Tropfen
			20NOV2009	YES	6:45	YES	17:30	3x täglich 40 Novaminsulfon Tropfen
			21NOV2009	YES	6:45	YES	17:30	3x täglich 40 Novaminsulfon Tropfen

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	22NOV2009	YES	7:00	YES	17:30	3x täglich 40 Novaminsulfon Tropfen
			23NOV2009	YES	6:45	YES	17:30	3x täglich 40 Novaminsulfon Tropfen
			24NOV2009	YES	6:45			3x täglich 40 Novaminsulfon Tropfen
			25NOV2009	YES	6:45	YES	17:30	3x täglich 40 Novaminsulfon Tropfen
			26NOV2009	YES	6:45	YES	17:30	3x täglich 40 Novaminsulfon Tropfen
			27NOV2009	YES	6:30	YES	17:30	3x täglich Novaminsulfon Tropfen
			28NOV2009	YES	6:45	YES	17:30	3x täglich Novaminsulfon Tropfen
			29NOV2009	YES	7:00	YES	18:00	3x täglich Novaminsulfon Tropfen
			30NOV2009	YES	6:45	YES	17:30	3x täglich Novaminsulfon Tropfen
			01DEC2009	YES	6:45	YES	17:30	3x täglich Novaminsulfon Tropfen
			02DEC2009	YES	6:45	YES	17:30	3x täglich Novaminsulfon Tropfen
			03DEC2009	YES	6:45	YES	17:30	3x täglich Novaminsulfon Tropfen
			04DEC2009	YES	6:45	YES	17:30	3x täglich Novaminsulfon Tropfen
			05DEC2009	YES	6:45	YES	19:30	3x täglich Novaminsulfon Tropfen
			06DEC2009	YES	7:00	YES	17:30	3x täglich Novaminsulfon Tropfen
			07DEC2009	YES	6:30	YES	17:30	3x täglich Novaminsulfon Tropfen
			08DEC2009	YES	6:30	YES	17:30	
			09DEC2009	YES	6:30	YES	17:30	
			10DEC2009	YES	6:30	YES	17:30	
			11DEC2009	YES	6:30	YES	19:30	
			12DEC2009	YES	6:30	YES	17:30	
			13DEC2009	YES	7:00	YES	18:00	
			14DEC2009	YES	6:30	YES	17:30	
			15DEC2009	YES	7:00		17:30	
			16DEC2009	YES	6:30	YES	19:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	17DEC2009	YES	6:30	YES	17:30	
			18DEC2009	YES	6:30	YES	17:30	
			19DEC2009	YES	6:30	YES	17:30	
			20DEC2009	YES	6:30	YES	17:30	
			21DEC2009	YES	6:30	YES	18:30	
			22DEC2009	YES	6:30	YES	17:30	
			23DEC2009	YES	5:30	YES	17:30	
			24DEC2009	YES	7:30	YES	17:00	
			25DEC2009	YES	7:30	YES	17:30	
			26DEC2009	YES	7:30	YES	17:30	
			27DEC2009	YES	7:30	YES	17:30	
			28DEC2009	YES	7:30	YES	18:00	
			29DEC2009	YES	7:00	YES	17:00	
			30DEC2009	YES	6:30		17:30	
			31DEC2009	YES	6:30	YES	17:00	
			01JAN2010	YES	7:30	YES	17:30	
			02JAN2010	YES	6:30	YES	17:30	
			03JAN2010	YES	6:30	YES	17:30	
			04JAN2010	YES	6:30	YES	18:00	
			05JAN2010	YES	6:30			
			05JAN2010			YES	17:30	Novaminsulfon Tropfen 3>30 Tropfen
			06JAN2010	YES	6:30	YES	18:00	
			07JAN2010	YES	6:30	YES	17:30	
			08JAN2010	YES	6:30	YES	17:30	
			09JAN2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	10JAN2010	YES	7:00	YES	18:00	
			11JAN2010	YES	7:00	YES	18:00	Enalapril-ct 10 mg 1x täglich
			12JAN2010	YES	6:30	YES	17:30	
			13JAN2010	YES	6:30	YES		
			14JAN2010	YES	6:30	YES	17:30	
			15JAN2010	YES	6:30	YES	17:30	
			16JAN2010	YES	6:30	YES	17:30	
			17JAN2010	YES	7:00	YES	18:00	
			18JAN2010	YES	6:30	YES	17:30	
			19JAN2010	YES	6:30	YES	17:30	
			20JAN2010	YES	6:30	YES	17:30	
			21JAN2010	YES	6:30	YES	17:30	
			22JAN2010	YES	6:30	YES	17:30	
			23JAN2010	YES	6:30	YES	18:00	
			24JAN2010	YES	7:30	YES	17:30	
			25JAN2010	YES	6:30	YES	17:30	
			26JAN2010	YES	6:30	YES	17:30	ab heute 1/3 Ena-Hexal 30 mg
			27JAN2010	YES	6:30	YES	17:30	
			28JAN2010	YES	6:30	YES	17:30	
			29JAN2010	YES	6:30	YES	17:30	
			30JAN2010	YES	6:30	YES	17:30	
			31JAN2010	YES	7:30	YES	17:30	
			01FEB2010	YES	6:30	YES	17:30	
			02FEB2010	YES	6:30	YES	17:30	
			03FEB2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	04FEB2010	YES	6:30	YES	17:30	
			05FEB2010	YES	6:30	YES	17:30	
			06FEB2010	YES	6:30	YES	17:30	
			07FEB2010	YES	7:30	YES	17:30	
			08FEB2010	YES	7:30	YES	17:30	
			09FEB2010	YES	7:30	YES	17:30	
			10FEB2010	YES	7:30	YES	17:30	
			11FEB2010	YES	7:30	YES	17:30	
			12FEB2010	YES	7:30	YES	17:30	
			13FEB2010	YES	7:30	YES	17:30	
			14FEB2010	YES	7:00	YES	17:30	
			15FEB2010	YES	7:00	YES	17:30	
			16FEB2010	YES	6:30	YES	17:30	
			17FEB2010	YES	6:30	YES	17:30	
			18FEB2010	YES	6:30	YES	17:30	
			19FEB2010	YES	6:30	YES	17:30	
			20FEB2010	YES	6:30	YES	17:30	
			21FEB2010	YES	7:00	YES	17:30	
			22FEB2010	YES	7:30	YES	17:30	
			23FEB2010	YES	7:30	YES	17:30	
			24FEB2010	YES	7:30	YES	17:30	
			25FEB2010	YES	7:30	YES	18:00	
			26FEB2010	YES	7:30	YES	17:30	
			27FEB2010	YES	7:30	YES	17:30	
			28FEB2010	YES	7:00	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	01MAR2010	YES	6:30	YES	18:00	
			02MAR2010	YES	6:30	YES	17:30	
			03MAR2010	YES	6:30	YES	17:30	
			04MAR2010	YES	6:30	YES	17:30	
			05MAR2010	YES	6:30	YES	17:30	
			06MAR2010	YES	6:30	YES	17:30	
			07MAR2010	YES	7:00	YES	17:30	
			08MAR2010	YES	6:30	YES	17:30	
			09MAR2010	YES	6:30	YES	17:30	
			10MAR2010	YES	6:30	YES	17:30	
			11MAR2010	YES	6:30	YES	17:30	
			12MAR2010	YES	6:30	YES	17:30	
			13MAR2010	YES	6:30	YES	17:30	
			14MAR2010	YES	7:00	YES	17:30	
			15MAR2010	YES	6:30	YES	17:30	
			16MAR2010	YES	6:30	YES	17:30	
			17MAR2010	YES	7:30	YES	17:30	
			18MAR2010	YES	7:30	YES	17:30	
			19MAR2010	YES	7:30	YES	17:30	
			20MAR2010	YES	7:30	YES	17:30	
			21MAR2010	YES	7:30	YES	17:30	
			22MAR2010	YES	7:30	YES	17:30	
			23MAR2010	YES	6:30	YES	17:30	
			24MAR2010	YES	6:30			
			25MAR2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	26MAR2010	YES	6:30	YES	17:30	
			27MAR2010	YES	6:30	YES	17:30	
			28MAR2010	YES	6:30	YES	17:30	
			29MAR2010	YES	6:30	YES	17:30	
			30MAR2010	YES	6:30	YES	17:30	
			31MAR2010	YES	6:30		17:30	
			01APR2010	YES	6:30	YES	17:30	
			02APR2010	YES	7:00	YES	17:30	
			03APR2010	YES	6:30	YES	17:30	
			04APR2010	YES	7:00	YES	17:30	
			05APR2010	YES	7:30	YES	17:30	
			06APR2010	YES	7:30	YES	17:30	
			07APR2010	YES	6:30	YES	17:30	
			08APR2010	YES	6:30	YES	18:00	
			09APR2010	YES	6:30	YES	17:30	
			10APR2010	YES	7:00	YES	17:30	
			11APR2010	YES	7:00	YES	17:30	
			12APR2010	YES	6:30	YES	17:30	
			13APR2010	YES	6:30	YES	17:30	
			14APR2010	YES	6:30	YES	17:30	
			15APR2010	YES	6:30	YES	17:30	
			16APR2010	YES	6:30	YES	17:30	
			17APR2010	YES	6:30	YES	17:30	
			18APR2010	YES	7:00	YES	17:30	
			19APR2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	20APR2010	YES	6:30	YES	17:30	
			21APR2010	YES	6:30	YES	17:30	
			22APR2010	YES	6:30	YES	17:30	
			23APR2010	YES	6:30	YES	17:30	
			24APR2010	YES	6:30	YES	17:30	
			25APR2010	YES	7:00	YES	17:30	
			26APR2010	YES	6:30	YES	17:30	
			27APR2010	YES	6:30	YES	17:30	
			28APR2010	YES	6:30	YES	17:30	
			29APR2010	YES	6:30	YES	17:30	
			30APR2010	YES	6:30	YES	17:30	
			01MAY2010	YES	6:30	YES	17:30	
			02MAY2010	YES	5:30	YES	18:00	
			03MAY2010	YES	6:30	YES	17:30	
			04MAY2010	YES	6:30	YES	17:30	
			05MAY2010	YES	6:30	YES	17:30	
			06MAY2010	YES	6:30	YES	17:30	
			07MAY2010	YES	6:30	YES	17:30	
			08MAY2010	YES	6:00	YES	20:00	
			09MAY2010	YES	7:30	YES	17:30	
			10MAY2010	YES	6:30	YES	17:30	
			11MAY2010	YES	6:30	YES	17:30	
			12MAY2010	YES	6:30	YES	17:30	
			13MAY2010	YES	6:30	YES	17:30	
			14MAY2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	15MAY2010	YES	6:30	YES	17:30	
			16MAY2010	YES	6:30	YES	17:30	
			17MAY2010	YES	6:30	YES	17:30	
			18MAY2010	YES	6:30	YES	17:30	
			19MAY2010	YES	6:30	YES	17:30	
			20MAY2010	YES	6:30	YES	17:30	
			21MAY2010	YES	6:30	YES	17:30	
			22MAY2010	YES	6:30	YES	17:30	
			23MAY2010	YES	7:00	YES	17:30	
			24MAY2010	YES	6:30	YES	17:30	
			25MAY2010	YES	6:30	YES	17:30	
			26MAY2010	YES	6:30	YES	17:30	
			27MAY2010	YES	6:30	YES	17:30	
			28MAY2010	YES	6:30	YES	17:30	
			29MAY2010	YES	6:30	YES	17:30	
			30MAY2010	YES	7:00	YES	17:30	
			31MAY2010	YES	6:30	YES	17:30	
			01JUN2010	YES	6:30	YES	17:30	
			02JUN2010	YES	6:30	YES	18:00	
			03JUN2010	YES	6:30	YES	17:30	
			04JUN2010	YES	6:30	YES	17:30	
			05JUN2010	YES	6:00	YES	18:00	
			06JUN2010	YES	6:30	YES	17:30	
			07JUN2010	YES	6:30	YES	18:00	
			08JUN2010	YES	6:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	09JUN2010	YES	6:30	YES	17:30	
			10JUN2010	YES	6:30	YES	17:30	
			11JUN2010	YES	6:30	YES	17:30	
			12JUN2010	YES	6:30	YES	17:30	
			13JUN2010	YES	7:00	YES	17:00	
			14JUN2010	YES	6:30	YES	17:30	
			15JUN2010	YES	6:30	YES	18:00	
			16JUN2010	YES	6:30			
			16JUN2010	YES	6:30	YES	17:30	
			17JUN2010	YES	6:30	YES	17:30	
			18JUN2010	YES	6:30	YES	17:30	
			19JUN2010	YES	6:30	YES	17:30	
			20JUN2010	YES	7:00	YES	17:30	
			21JUN2010	YES	6:00	YES	18:00	
			22JUN2010	YES	6:30	YES	18:30	
			23JUN2010	YES	6:30	YES	18:30	
			24JUN2010	YES	6:30	YES	18:30	
			25JUN2010	YES	6:30	YES	17:30	
			26JUN2010	YES	6:30	YES	17:30	
			27JUN2010	YES	6:00	YES	18:30	
			28JUN2010	YES	6:30	YES	17:30	
			29JUN2010	YES	6:30	YES	17:30	
			30JUN2010	YES	6:30	YES	17:30	
			01JUL2010	YES	6:30	YES	17:30	
			02JUL2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	03JUL2010	YES	6:30	YES	17:30	
			04JUL2010	YES	7:30	YES	18:00	
			05JUL2010	YES	7:30	YES	17:30	
			06JUL2010	YES	6:30	YES	17:30	
			07JUL2010	YES	6:30	YES	17:30	
			08JUL2010	YES	6:30	YES	17:30	
			09JUL2010	YES	6:30	YES	17:30	
			10JUL2010	YES	6:30	YES	18:00	
			11JUL2010	YES	7:00	YES	18:00	
			12JUL2010	YES	6:30	YES	17:30	
			13JUL2010	YES	6:30	YES	17:30	
			14JUL2010	YES	6:30	YES	17:30	
			15JUL2010	YES	6:30	YES	17:30	
			16JUL2010	YES	6:30	YES	17:30	
			17JUL2010	YES	6:30	YES	17:30	
			18JUL2010	YES	6:30	YES	17:30	
			19JUL2010	YES	6:30	YES	17:30	
			20JUL2010	YES	6:30	YES	17:30	
			21JUL2010	YES	6:30	YES	17:30	
			22JUL2010	YES	6:30	YES	17:30	
			23JUL2010	YES	6:30	YES	17:30	
			24JUL2010	YES	6:30	YES	17:30	
			25JUL2010	YES	7:30	YES	17:30	
			26JUL2010	YES	6:30	YES	17:30	
			27JUL2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	28JUL2010	YES	6:30	YES	17:30	
			29JUL2010	YES	6:30	YES	17:30	
			30JUL2010	YES	6:30	YES	17:30	
			31JUL2010	YES	6:30	YES	18:00	
			01AUG2010	YES	7:00	YES	18:00	
			02AUG2010	YES	6:30	YES	17:30	
			03AUG2010	YES	6:30	YES	17:30	
			04AUG2010	YES	6:30	YES	17:30	
			05AUG2010	YES	6:30	YES	17:30	
			06AUG2010	YES	6:30		17:30	
			07AUG2010	YES	7:00	YES	18:00	
			08AUG2010	YES	7:00	YES	17:30	
			09AUG2010	YES	6:30	YES	17:30	
			10AUG2010	YES	6:30	YES	17:30	
			11AUG2010	YES	6:30	YES	17:30	
			12AUG2010	YES	6:30	YES	17:30	
			13AUG2010	YES	6:30	YES	17:30	
			14AUG2010	YES	6:30	YES	17:30	
			15AUG2010	YES	7:00	YES	17:30	
			16AUG2010	YES	7:30	YES	17:30	
			17AUG2010	YES	6:30	YES	17:30	
			18AUG2010	YES	6:30	YES	17:30	
			19AUG2010	YES	6:30	YES	17:30	
			20AUG2010	YES	6:30	YES	17:30	
			21AUG2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	22AUG2010	YES	6:30	YES	17:30	
			23AUG2010	YES	6:30	YES	18:00	
			24AUG2010	YES	7:00	YES	18:00	
			25AUG2010	YES	7:00	YES	18:00	
			26AUG2010	YES	6:30	YES	18:00	
			27AUG2010	YES	6:30	YES	17:30	
			28AUG2010	YES	6:30	YES	17:30	
			29AUG2010	YES	7:00	YES	18:00	
			30AUG2010	YES	6:30		17:30	
			31AUG2010	YES	6:30	YES	17:30	
			01SEP2010	YES	6:30	YES	17:30	
			02SEP2010	YES	6:30	YES	17:30	
			03SEP2010	YES	6:30	YES	18:00	
			04SEP2010	YES	6:30	YES	17:30	
			05SEP2010	YES	7:00	YES	17:30	
			06SEP2010	YES	6:30	YES	17:30	
			07SEP2010	YES	6:30	YES	17:30	
			08SEP2010	YES	6:30	YES	17:30	
			09SEP2010	YES	6:30	YES	17:30	
			10SEP2010	YES	6:30	YES	17:30	
			11SEP2010	YES	6:30	YES	17:30	
			12SEP2010	YES	7:00	YES	18:00	
			13SEP2010	YES	6:30	YES	17:30	
			14SEP2010	YES	6:30	YES	17:30	
			15SEP2010	YES	6:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	041	12	16SEP2010	YES	6:30	YES	17:30	
			17SEP2010	YES	6:30	YES	17:30	
			18SEP2010	YES	6:30	YES	17:30	
			19SEP2010	YES	7:00	YES	16:30	
			20SEP2010	YES	6:30	YES	17:30	
			21SEP2010	YES	6:30	YES	18:00	
			22SEP2010	YES	6:30	YES	17:30	
			23SEP2010	YES	6:30	YES	17:30	
			24SEP2010	YES	6:30	YES	17:30	
			25SEP2010	YES	6:30	YES	18:00	
			26SEP2010	YES	7:00	YES	18:00	
			27SEP2010	YES	6:30	YES	18:00	
			28SEP2010	YES	6:30	YES	18:00	
			29SEP2010	YES	6:30	YES	18:00	
			30SEP2010	YES	6:30	YES	18:00	
			01OCT2010	YES	6:30	YES	18:00	
			02OCT2010	YES	6:30	YES	17:30	
			03OCT2010	YES	7:00	YES	18:00	
			04OCT2010	YES	6:30	YES	17:30	
			05OCT2010	YES	6:30	YES	17:30	
			06OCT2010	YES	6:30			
	044	12	03DEC2009	YES	7:40	YES	19:30	
			04DEC2009	YES	8:00	YES	19:35	
			05DEC2009	YES	7:20	YES	22:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	06DEC2009	YES	8:10	YES	19:45	
			07DEC2009	YES	7:30	YES	19:30	
			08DEC2009	YES	8:00	YES	19:30	
			09DEC2009	YES	7:30	YES	19:30	
			10DEC2009	YES	7:00			
			11DEC2009	YES	8:30	YES	22:15	
			12DEC2009	YES	8:45	YES	20:45	
			13DEC2009	YES	8:15	YES	19:00	
			14DEC2009	YES	7:30	YES	19:45	
			15DEC2009	YES	7:00	YES	19:15	
			16DEC2009	YES	7:30	YES	19:30	
			17DEC2009	YES	8:45	YES	20:00	
			18DEC2009	YES	7:10	YES	20:00	
			19DEC2009	YES	7:45	YES	22:00	
			20DEC2009	YES	8:25	YES	20:35	
			21DEC2009	YES	9:00	YES	21:15	
			22DEC2009	YES	8:45	YES	19:45	
			23DEC2009	YES	7:00	YES	20:00	
			24DEC2009	YES	9:00	YES	19:15	
			25DEC2009	YES	8:45	YES	21:00	
			26DEC2009	YES	8:30	YES	18:15	
			27DEC2009	YES	8:45		22:00	
			28DEC2009	YES	9:15	YES	19:45	
			29DEC2009	YES	8:30	YES	18:45	
			30DEC2009	YES	8:30	YES	19:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	01JAN2010	YES	9:30	YES	19:30	
			02JAN2010	YES	9:30	YES	23:30	
			03JAN2010	YES	8:05	YES	20:00	
			04JAN2010	YES	7:45	YES	20:00	
			05JAN2010	YES	8:00	YES	20:00	
			06JAN2010	YES	7:45	YES	20:15	
			07JAN2010	YES	7:15			
			07JAN2010	YES	7:30	YES	20:00	
			08JAN2010	YES	9:00	YES	20:00	
			09JAN2010	YES	8:00	YES	20:00	
			10JAN2010	YES	8:15	YES	20:00	
			11JAN2010	YES	7:30	YES	19:30	
			12JAN2010	YES	8:30	YES	19:00	
			13JAN2010	YES	8:10		19:30	
			14JAN2010	YES	8:30	YES	19:39	
			15JAN2010	YES	7:00	YES	19:30	
			16JAN2010	YES	8:45			?
			17JAN2010	YES	8:20	YES	19:30	
			18JAN2010	YES	8:00	YES	19:45	
			19JAN2010	YES	7:30	YES	19:00	
			20JAN2010	YES	7:30	YES	19:15	
			21JAN2010	YES	7:10	YES	19:15	
			22JAN2010	YES	7:45	YES	19:00	
			23JAN2010	YES	8:15			
			24JAN2010	YES	8:00	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	25JAN2010	YES	7:30	YES	21:15	
			26JAN2010	YES	7:45	YES	19:00	
			27JAN2010	YES	8:00	YES	19:00	
			28JAN2010	YES	7:30	YES	19:39	
			29JAN2010	YES	8:00	YES	20:42	
			30JAN2010	YES	7:45	YES	19:30	
			31JAN2010	YES	8:30	YES	20:00	
			01FEB2010	YES	7:37	YES	19:00	
			02FEB2010	YES	8:00	YES	19:00	
			03FEB2010	YES	8:30	YES	19:00	
			04FEB2010	YES	8:20	YES	19:30	
			05FEB2010	YES	7:30	YES	19:30	
			06FEB2010	YES	8:45	YES	20:00	
			07FEB2010	YES	7:30	YES	20:00	
			08FEB2010	YES	8:30	YES	19:30	
			09FEB2010	YES	8:00	YES	19:00	
			10FEB2010	YES	8:30	YES	19:00	
			11FEB2010	YES	8:00	YES	19:00	
			12FEB2010	YES	7:45	YES	19:00	
			13FEB2010	YES	7:30	YES	18:45	
			14FEB2010	YES	7:30	YES	19:30	
			15FEB2010	YES	7:45	NO		vergessen
			16FEB2010	YES	8:20	YES	19:00	
			17FEB2010	YES	8:15	YES	19:10	
			18FEB2010	YES	8:20	YES	18:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	19FEB2010	YES	7:45	YES	19:00	
			20FEB2010	YES	8:00	YES	19:00	
			21FEB2010	YES	8:10	YES	19:00	
			22FEB2010	YES		YES	18:45	
			23FEB2010	YES	7:45	YES	19:00	
			24FEB2010	YES	8:10			
			24FEB2010			YES	18:00	24 Februar
			25FEB2010	YES	8:00	YES	19:00	
			26FEB2010	YES	8:30	YES	19:30	
			27FEB2010	YES	8:30	YES	20:00	
			28FEB2010	YES	8:15	YES	19:00	
			01MAR2010	YES	7:30	YES	18:30	
			02MAR2010	YES	7:00	YES	19:00	
			03MAR2010	YES	7:30	YES	19:00	
			04MAR2010	YES	8:00	YES	19:00	
			05MAR2010	YES	8:30	YES	19:00	
			06MAR2010	YES	8:15	YES	19:30	
			07MAR2010	YES	7:45	YES	18:30	
			08MAR2010	YES	7:45	YES	19:00	
			09MAR2010	YES	8:00	YES	19:00	
			10MAR2010	YES	7:45	YES	18:45	
			11MAR2010	YES	8:00	YES	19:00	
			12MAR2010	YES	7:30	YES	18:30	
			13MAR2010	YES	7:30	YES	19:00	
			14MAR2010	YES	8:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	15MAR2010	YES	7:00	YES	18:30	
			16MAR2010	YES	7:00	NO		vergessen
			17MAR2010	YES	7:30	YES	18:00	
			18MAR2010	YES	7:30	YES	18:00	
			19MAR2010	YES	8:00	NO		vergessen
			20MAR2010	YES	8:00	YES	19:00	
			21MAR2010	YES	8:00	YES	18:45	
			22MAR2010	YES	7:30	YES	18:45	
			23MAR2010	YES	8:00	YES	19:00	
			24MAR2010	YES	8:00	YES	19:00	
			25MAR2010	YES	9:00	YES	18:45	
			26MAR2010	YES	8:00	YES	19:00	
			27MAR2010	YES	8:00	YES	19:30	
			28MAR2010	YES	7:00	YES	18:45	
			29MAR2010	YES	7:30	YES	18:45	
			30MAR2010	YES	7:00	YES	19:00	
			31MAR2010	YES	7:30	YES	19:00	
			01APR2010	YES	8:00	YES	18:00	
			02APR2010	YES	7:15	YES	18:30	
			03APR2010	YES	7:00	YES	18:00	
			04APR2010	YES	7:30	YES	19:00	
			05APR2010	YES	7:00	YES	18:30	
			06APR2010	YES	8:00	YES	18:30	
			07APR2010	YES	7:00	YES	18:30	
			08APR2010	YES	7:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	09APR2010	YES	7:00	YES	18:30	
			10APR2010	YES	7:00	YES	19:00	
			11APR2010	YES	7:30	YES	19:00	
			12APR2010	YES	8:00	YES	18:30	
			13APR2010	YES	7:30	NO		vergessen
			14APR2010	YES	9:00	YES		
			15APR2010	YES	8:20	YES	19:00	
			16APR2010	YES	7:30	YES	18:50	
			17APR2010	YES	7:00	YES	19:00	
			18APR2010	YES	7:40	YES	19:00	
			19APR2010	YES	8:00	YES	18:30	
			20APR2010	YES	7:00	YES	19:00	
			21APR2010	YES	7:15	YES	19:15	
			22APR2010	YES	7:15	YES	19:00	
			23APR2010	YES	7:15	YES	19:00	
			24APR2010	YES	7:15	YES	19:00	
			25APR2010	YES	7:15	YES	19:15	
			26APR2010	YES	7:30	YES	18:30	
			27APR2010	YES	7:00	YES	18:45	
			28APR2010	YES	8:00	YES	19:00	
			29APR2010	YES	7:30	YES	18:45	
			30APR2010	YES	7:30	YES	19:00	
			01MAY2010	YES	7:00	YES	18:30	
			02MAY2010	YES	7:30	YES	18:30	
			03MAY2010	YES	7:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	04MAY2010	YES	7:30	YES	18:45	
			05MAY2010	YES	7:30	YES	18:45	
			06MAY2010	YES	7:30	YES	18:45	
			07MAY2010	YES	7:00	YES	18:45	
			08MAY2010	YES	7:00	YES	18:30	
			09MAY2010	YES	7:00	YES	18:30	
			10MAY2010	YES	7:30	YES	19:00	
			11MAY2010	YES	7:15	YES	18:45	
			12MAY2010	YES	7:00	YES	18:30	
			13MAY2010	YES	7:00	YES	18:45	
			14MAY2010	YES	7:30	YES	19:00	
			15MAY2010	YES	7:15	YES	18:45	
			16MAY2010	YES	7:30	NO		vergessen
			17MAY2010	YES	7:00	YES	19:00	
			18MAY2010	YES	7:00	YES	18:45	
			19MAY2010	YES	7:45	YES	19:30	
			20MAY2010	YES	7:30	YES	18:45	
			21MAY2010	YES	7:30	YES	18:30	
			22MAY2010	YES	7:00	YES	20:00	
			23MAY2010	YES	7:30	YES	19:00	
			24MAY2010	YES	7:30	YES	20:00	
			25MAY2010	YES	7:50	YES	19:45	
			26MAY2010	YES	6:50			
			26MAY2010			YES	19:00	
			27MAY2010	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	28MAY2010	YES	7:30	YES	18:00	
			29MAY2010	YES	7:30	YES	18:00	
			30MAY2010	YES	7:30	YES	18:15	
			31MAY2010	YES	7:30	YES	18:00	
			01JUN2010	YES	7:00	YES	18:30	
			02JUN2010	YES	7:30	YES	18:00	
			03JUN2010	YES	7:30	YES	18:30	
			04JUN2010	YES	7:30	YES	18:00	
			05JUN2010	YES	7:00	YES	18:30	
			06JUN2010	YES	7:00	YES	18:30	
			07JUN2010	YES	7:45	YES	18:30	
			08JUN2010	YES	7:30	YES	18:30	
			09JUN2010	YES	7:00	YES	19:00	
			10JUN2010	YES	7:15	YES	18:45	
			11JUN2010	YES	7:30	YES	18:30	
			12JUN2010	YES	7:45	YES	17:45	
			13JUN2010	YES	7:30	YES	18:30	
			14JUN2010	YES	7:30	YES	18:30	
			15JUN2010	YES	7:45	YES	18:45	
			16JUN2010	YES	7:30	YES	18:00	
			17JUN2010	YES	7:30	YES	18:30	
			18JUN2010	YES	7:30	YES	18:30	
			19JUN2010	YES	7:30	YES	18:15	
			20JUN2010	YES	7:45	YES	18:00	
			21JUN2010	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	22JUN2010	YES	8:00	YES	18:30	
			23JUN2010	YES	7:45	YES	18:00	
			24JUN2010	YES	7:45	YES	18:30	
			25JUN2010	YES	7:00	YES	18:00	
			26JUN2010	YES	7:30	YES	18:30	
			27JUN2010	YES	7:30	YES	18:00	
			28JUN2010	YES	7:30	YES	18:00	
			29JUN2010	YES	7:30	YES	18:00	
			30JUN2010	YES	7:30	YES	18:30	
			01JUL2010	YES	7:45	YES	18:00	
			02JUL2010	YES	7:30	YES	18:30	
			03JUL2010	YES	7:45	YES	18:00	
			04JUL2010	YES	7:45	YES	18:15	
			05JUL2010	YES	7:00	YES	18:00	
			06JUL2010	YES	7:30	YES	18:00	
			07JUL2010	YES	7:00	YES	18:00	
			08JUL2010	YES	7:45	YES	18:30	
			09JUL2010	YES	7:15	YES	18:00	
			10JUL2010	YES	7:30	YES	18:00	
			11JUL2010	YES	7:30	YES	18:00	
			12JUL2010	YES	7:30	YES	18:00	
			13JUL2010	YES	7:30	YES	18:00	
			14JUL2010	YES	7:30	YES	18:00	
			15JUL2010	YES	7:30	YES	18:00	
			16JUL2010	NO		YES	18:00	vergessen

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	17JUL2010	YES	7:30	YES	18:00	
			18JUL2010	YES	7:30	YES	18:30	
			19JUL2010	YES	7:30	YES	18:00	
			20JUL2010	NO		YES	18:30	vergessen
			21JUL2010	YES	7:00	YES	18:00	
			22JUL2010	YES	7:00	YES	18:00	
			23JUL2010	YES	7:00	YES	18:00	
			24JUL2010	YES	7:30	NO	18:00	vergessen
			25JUL2010	YES	7:30	YES	18:30	
			26JUL2010	YES	7:45	YES	18:30	
			27JUL2010	YES	7:30	YES	18:00	
			28JUL2010	YES	7:30	YES	18:00	
			29JUL2010	YES	7:30	YES	18:30	
			30JUL2010	YES	7:30	YES	18:30	
			31JUL2010	YES	7:30	YES	18:00	
			01AUG2010	YES	7:30	YES	18:00	
			02AUG2010	YES	7:30	YES	18:00	
			03AUG2010	YES	7:30	YES	18:00	
			04AUG2010	YES	7:30	YES	18:00	
			05AUG2010	YES	7:30	YES	18:00	
			06AUG2010	YES	7:00	YES	18:30	
			09AUG2010	YES	7:30	YES	18:30	
			10AUG2010	YES	7:30	YES	18:00	
			11AUG2010	YES	7:30	YES	18:00	
			12AUG2010	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	13AUG2010	YES	7:30	YES	18:30	
			14AUG2010	YES	7:00	YES	18:00	
			15AUG2010	YES	7:00	YES	18:00	
			16AUG2010	YES	7:30	YES	18:15	
			17AUG2010	YES	7:30	YES	18:00	
			18AUG2010	YES	7:15	YES	18:00	
			19AUG2010	YES	7:30	YES	18:00	
			20AUG2010	YES	7:30	YES	18:30	
			21AUG2010	YES	7:30	YES	18:30	
			22AUG2010	YES	7:30	YES	18:30	
			23AUG2010	YES	7:30	YES	18:30	
			24AUG2010	YES	8:00	YES	19:00	
			25AUG2010	YES	7:15	YES	18:30	
			26AUG2010	YES	7:30	YES	18:45	
			27AUG2010	YES	7:30	YES	18:30	
			28AUG2010	YES	7:30	YES	18:30	
			29AUG2010	YES	7:00	YES	18:30	
			30AUG2010	YES	7:00	YES	18:30	
			31AUG2010	YES	7:30	YES	18:30	
			01SEP2010	YES	7:30	YES	18:30	
			02SEP2010	YES	7:00	YES	18:30	
			03SEP2010	YES	7:30	YES	18:00	
			04SEP2010	YES	7:30	YES	18:30	
			05SEP2010	NO		NO		
			06SEP2010	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	07SEP2010	YES	7:30	YES	18:00	
			08SEP2010	YES	7:30	YES	18:30	
			09SEP2010	YES	7:30	YES	18:30	
			10SEP2010		7:00		18:45	
			10SEP2010	YES	7:30	YES	18:30	x
			11SEP2010	YES	7:30	YES	18:30	
			11SEP2010	YES	7:30	YES	18:30	x
			12SEP2010	YES	7:45	YES	18:45	
			12SEP2010	YES	7:00	YES	18:00	x
			13SEP2010	YES	7:15	YES	18:15	
			13SEP2010	YES	7:30	YES	19:00	x
			14SEP2010	YES	8:00	YES	18:30	
			15SEP2010	YES	7:30	YES	18:45	
			16SEP2010	YES	7:30	YES	18:45	
			17SEP2010	YES	7:30	YES	18:30	
			18SEP2010	YES	7:30	YES	18:30	
			19SEP2010	YES	7:30	YES	18:30	
			20SEP2010	YES	7:30	YES	18:30	
			21SEP2010	YES	7:30	YES	18:30	
			22SEP2010	YES	7:30	YES	18:30	
			23SEP2010	YES	7:45	YES	18:45	
			24SEP2010	YES	7:30	YES	18:30	
			25SEP2010	YES	7:30	YES	18:30	
			26SEP2010	YES	7:45	YES	18:45	
			27SEP2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	28SEP2010	YES	7:00	YES	18:30	
			29SEP2010	YES	7:30	YES	18:30	
			30SEP2010	YES	7:45	YES	18:45	
			01OCT2010	YES		YES		
			02OCT2010	YES		YES		
			03OCT2010	YES		YES		
			04OCT2010	YES		YES		
			05OCT2010	NO		YES	19:00	x
			06OCT2010	YES	7:30	YES	18:30	
			07OCT2010	YES	7:30	YES	18:30	
			08OCT2010	YES	7:30	YES	18:45	
			09OCT2010	YES	7:00	YES	18:45	
			10OCT2010	YES	7:30	YES	18:45	
			11OCT2010	YES	8:00	YES	18:00	
			12OCT2010	YES	7:30	YES	18:30	
			13OCT2010	YES	7:30	YES	18:45	
			14OCT2010	YES	7:30	YES	18:30	
			15OCT2010	YES	7:30	YES	18:30	
			16OCT2010	YES	7:30	YES	18:30	
			17OCT2010	YES	7:30	YES	18:45	
			18OCT2010	YES	7:30	YES	18:45	
			19OCT2010	YES	7:30	YES	19:00	
			20OCT2010	YES	7:30	YES	19:00	
			21OCT2010	YES		YES	18:30	
			22OCT2010	YES		YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	23OCT2010	YES		YES	18:45	
			24OCT2010	YES		YES	18:45	
			25OCT2010	YES	7:30	YES	18:45	
			26OCT2010	YES	7:00	YES	18:45	
			27OCT2010	YES	7:30	YES	18:30	
			28OCT2010	YES	7:15	YES	18:30	
			29OCT2010	YES	7:30	YES	18:30	
			30OCT2010	YES	7:30	YES	18:30	
			31OCT2010	YES	7:30	YES	18:30	
			01NOV2010	YES	7:15	YES	18:45	
			02NOV2010	YES	7:30	YES	18:45	
			03NOV2010	YES	7:45	YES	18:45	
			04NOV2010	YES	7:00	YES	18:30	
			05NOV2010	YES	7:30	YES	18:30	
			06NOV2010	YES	7:15	YES	18:45	
			07NOV2010	YES	7:15	YES	18:30	
			08NOV2010	YES	8:00	YES	18:45	
			09NOV2010	YES	7:30	YES	18:30	
			10NOV2010	YES	7:30	YES	18:30	
			11NOV2010	YES	7:45	YES	18:45	
			12NOV2010	YES	7:30	YES	18:30	
			13NOV2010	YES	7:45	YES	18:45	
			14NOV2010	YES	7:30	YES	19:00	
			15NOV2010	YES	7:45	YES	19:00	
			16NOV2010	YES	7:30	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	044	12	17NOV2010	YES	8:00	YES	18:00	
			18NOV2010	YES	7:30	YES	18:45	
			19NOV2010	YES	7:45	YES	18:30	
			20NOV2010	YES	7:30	YES	18:30	
			21NOV2010	YES	7:30	YES	18:30	
			22NOV2010	YES	7:30	YES	18:30	
			23NOV2010	YES		YES		
			24NOV2010		7:30		18:30	
			25NOV2010	YES	7:30	YES	18:30	
			26NOV2010	YES	7:15	YES	18:45	
			27NOV2010	YES	7:30	YES	18:30	
			28NOV2010	YES	7:15	YES	18:30	
			29NOV2010	YES	7:30	YES	18:30	
			30NOV2010	YES	7:30	YES	18:30	
			01DEC2010	YES	7:30	YES		
	045	11	22DEC2009	YES	7:00	YES	19:00	
			23DEC2009	YES	7:30	YES	19:30	
			24DEC2009	YES	8:00	YES	20:00	
			25DEC2009	YES	8:40	YES	19:00	
			26DEC2009	YES	8:30	YES	23:30	
			27DEC2009	YES	9:30	YES	20:00	
			28DEC2009	YES	7:45	YES	20:00	
			29DEC2009	YES	8:50	YES	19:00	
			30DEC2009	YES	7:50	YES	7:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	31DEC2009	YES	8:00	YES	19:00	
			01JAN2010	YES	9:00	YES	18:30	
			02JAN2010	YES	9:30	YES	19:00	
			03JAN2010	YES	8:00	YES	19:00	
			04JAN2010	YES	8:00	YES	18:30	
			05JAN2010	YES	7:20	YES	19:20	
			06JAN2010	YES	7:00	YES	18:50	
			07JAN2010	YES	7:15	YES	19:00	
			08JAN2010	YES	8:00	YES	20:00	
			09JAN2010	YES	7:00	YES	18:00	
			10JAN2010	YES	7:30	YES	18:00	
			11JAN2010	YES	7:00	YES	18:30	
			12JAN2010	YES	6:30	YES	19:00	
			13JAN2010	YES	7:30	YES	18:20	
			14JAN2010	YES	7:00	YES	19:20	
			15JAN2010	YES	8:30	YES	18:00	
			16JAN2010	YES	8:00	YES	17:30	
			17JAN2010	YES	7:30	YES	18:30	
			18JAN2010	YES	6:00			
			18JAN2010	YES		YES	18:00	Tablette für morgens im vorherigen Patientenbuch angegeben!
			19JAN2010	YES	7:30	YES	19:00	
			20JAN2010	YES	7:00	YES	18:00	
			21JAN2010	YES	6:30	YES	17:30	
			22JAN2010	YES	7:45	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	23JAN2010	YES	8:00	YES	16:30	
			24JAN2010	YES	8:30	YES	18:40	
			25JAN2010	YES	7:00	YES	17:30	
			26JAN2010	YES	6:50	YES	18:30	
			27JAN2010	YES	8:30	YES	19:00	
			28JAN2010	YES	7:00	YES	18:50	
			29JAN2010	YES	7:30	YES	18:00	
			30JAN2010	YES	7:00	NO		Erbrechen! Magen-Darm-Problem
			31JAN2010	NO		NO		Erbrechen! Magen-Darm-Problem
			01FEB2010	NO		NO		Erbrechen! Magen-Darm-Problem
			02FEB2010	NO		NO		Erbrechen! Magen-Darm-Problem
			03FEB2010	NO		NO		Erbrechen! Magen-Darm-Problem
			04FEB2010	YES	8:30	YES	18:00	
			05FEB2010	YES	7:30	YES	19:30	
			06FEB2010	YES	8:15	YES	18:30	
			07FEB2010	YES	6:00	YES	18:00	
			08FEB2010	YES	7:30	YES	17:30	
			09FEB2010	YES	6:45	YES	18:00	
			10FEB2010	YES	6:30	YES	17:30	
			11FEB2010	YES	7:30	YES	17:30	
			12FEB2010	YES	7:00	YES	17:30	
			13FEB2010	YES	8:30	YES	18:15	
			14FEB2010	YES	7:30	YES	18:00	
			15FEB2010	YES	7:00	YES	18:30	
			16FEB2010	YES	8:00	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	17FEB2010	YES	8:20	YES	17:30	
			18FEB2010	YES	6:30	YES	18:00	
			19FEB2010	YES	7:00	YES	17:40	
			20FEB2010	YES	8:00	YES	18:30	
			21FEB2010	YES	7:00	YES	17:30	
			22FEB2010	YES	7:30	YES	17:00	
			23FEB2010	YES	7:30	YES	18:00	
			24FEB2010	YES	8:00	YES	18:00	
			25FEB2010	YES	9:00	YES	19:00	
			26FEB2010	YES	7:30	YES	18:00	
			27FEB2010	YES	6:30	YES	18:30	
			28FEB2010	YES	7:30	YES	18:00	
			01MAR2010	YES	7:30	YES	19:00	
			02MAR2010	YES	7:00	YES	18:00	
			03MAR2010	YES	9:00	YES	18:30	
			04MAR2010	YES	7:30	YES	17:30	
			05MAR2010	YES	7:00	YES	17:30	
			06MAR2010	YES	7:00	YES	22:00	<- nach dem Essen!
			07MAR2010	YES	8:30	YES	17:30	
			08MAR2010	YES	7:45	YES	18:30	
			09MAR2010	YES	7:40	YES	19:00	
			10MAR2010	YES	7:00	YES	18:30	
			11MAR2010	YES	7:15	YES	17:30	
			12MAR2010	YES	7:00	YES	18:30	
			13MAR2010	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	14MAR2010	YES	8:00	YES	19:00	
			15MAR2010	YES	6:00	YES		
			15MAR2010			YES	18:00	
			16MAR2010	YES	8:30	YES	17:30	
			17MAR2010	YES	8:00	YES	17:30	
			18MAR2010	YES	9:00	YES	17:30	
			19MAR2010	YES	7:30	YES	18:00	
			20MAR2010	YES	7:00	YES	18:30	
			21MAR2010	YES	7:00	YES	22:00	
			22MAR2010	YES	7:00	YES	18:30	
			23MAR2010	YES	8:30	YES	18:00	
			24MAR2010	YES	7:00	YES	18:00	
			25MAR2010	YES	7:00	YES	17:30	
			26MAR2010	YES	7:30	YES	17:30	
			27MAR2010	YES	9:00	YES	17:00	
			28MAR2010	YES	8:30	YES	18:30	
			29MAR2010	YES	8:00	YES	18:00	
			30MAR2010	YES	8:00	YES	17:00	
			31MAR2010	YES	7:30	YES	17:30	
			01APR2010	YES	7:00	YES	18:30	
			02APR2010	YES	8:30	YES	18:30	
			03APR2010	YES	8:30	YES	17:30	
			04APR2010	YES	7:00	YES	17:30	
			05APR2010	YES	8:00	YES	19:00	
			06APR2010	YES	7:30	YES	22:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	07APR2010	YES	7:30	YES	18:30	
			08APR2010	YES	8:00	YES	18:00	
			09APR2010	YES	9:00	YES	17:30	
			10APR2010	YES	10:00	YES	17:30	
			11APR2010	YES	9:00	YES	18:00	
			12APR2010	YES	8:00	YES	17:30	
			13APR2010	YES	7:00	YES	17:00	
			14APR2010	YES	7:00	YES	17:00	
			15APR2010	YES	8:30	YES	18:00	
			16APR2010	YES	6:30	YES	18:00	
			17APR2010	YES	7:30	YES	17:30	
			18APR2010	YES	6:00	YES	18:00	
			19APR2010	YES	7:30	YES	20:00	
			20APR2010	YES	8:00	YES	18:30	
			21APR2010	YES	7:00	YES	18:40	
			22APR2010	YES	7:00	YES	18:00	
			23APR2010	YES	7:30	YES	17:30	
			24APR2010	YES	7:30	YES	21:00	
			25APR2010	YES	8:00	YES	17:30	
			26APR2010	YES	9:00	YES	18:00	
			27APR2010	YES	7:30	YES	18:30	
			28APR2010	YES	6:30	YES	20:00	
			29APR2010	YES	8:00	YES	20:00	
			30APR2010	YES	8:30	YES	18:00	
			01MAY2010	YES	9:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	02MAY2010	YES	7:30	NO		Vergessen!
			03MAY2010	YES	7:00	YES	17:30	
			04MAY2010	YES	8:30	YES	16:30	
			05MAY2010	YES	8:00	YES	18:00	
			06MAY2010	YES	7:00	YES	18:30	
			07MAY2010	YES	6:00	YES	18:30	
			08MAY2010	YES	7:00	YES	18:00	
			09MAY2010	YES	8:00	YES	19:00	
			10MAY2010	YES	7:30	YES	18:00	
			11MAY2010	YES	8:00	YES	18:30	
			12MAY2010	YES	8:00	NO		Blutung im linken Auge.
			13MAY2010	NO		NO		Blutung im linken Auge.
			14MAY2010	NO		NO		Blutung im linken Auge.
			15MAY2010	NO		NO		Blutung im linken Auge.
			16MAY2010	NO		NO		Blutung im linken Auge. 9 Tabletten wurden nicht eingenommen! 17/05 = Augenarztbesuch: Diagnose Glaskörperablösung.
			17MAY2010	YES	12:00	YES	19:00	
			18MAY2010	YES	7:30	YES	18:00	
			19MAY2010	YES	7:00	YES	18:00	
			20MAY2010	YES	7:00	YES	18:00	
			21MAY2010	YES	8:30	YES	19:30	
			22MAY2010	YES	8:00	YES	18:30	
			23MAY2010	YES	8:00	YES	18:00	
			24MAY2010	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	25MAY2010	YES	7:30	YES	18:30	
			26MAY2010	YES	8:00	YES	18:00	
			27MAY2010	YES	7:00	YES	17:00	
			28MAY2010	YES	7:00	YES	17:00	
			29MAY2010	YES	8:30	YES	17:00	
			30MAY2010	YES	7:30	YES	17:30	
			31MAY2010	YES	7:00	YES	18:00	
			01JUN2010	YES	7:30	NO		Vergessen!
			02JUN2010	YES	7:30	YES	18:30	
			03JUN2010	YES	8:30	YES	19:00	
			04JUN2010	YES	8:00	YES	18:00	
			05JUN2010	YES	7:30	YES	17:30	
			06JUN2010	YES	8:00	YES	17:30	
			07JUN2010	YES	6:00			
			07JUN2010	YES		YES	18:00	Uhrzeit morgens: letztes Patientenbuch
			08JUN2010	YES	7:00	YES	18:30	
			09JUN2010	YES	7:00	YES	17:00	
			10JUN2010	YES	7:30	YES	17:00	
			11JUN2010	YES	7:30	YES	17:30	
			12JUN2010	YES	8:00	NO		vergessen!
			13JUN2010	YES	7:30	YES	18:30	
			14JUN2010	YES	7:30	YES	18:00	
			15JUN2010	YES	8:30	YES	19:00	
			16JUN2010	YES	7:30	YES	20:00	
			17JUN2010	YES	7:30	YES	16:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	18JUN2010	YES	7:30	YES	18:00	
			19JUN2010	YES	8:00	YES	18:30	
			20JUN2010	YES	7:30	YES	18:00	
			21JUN2010	YES	10:00	YES	19:00	
			22JUN2010	YES	8:30	YES	17:30	
			23JUN2010	YES	8:00	YES	18:00	
			24JUN2010	YES	8:00	YES	19:30	
			25JUN2010	YES	7:30	YES	18:30	
			26JUN2010	YES	9:00	NO		vergessen!
			27JUN2010	YES	8:00	YES	18:00	
			28JUN2010	YES	7:30	YES	18:30	
			29JUN2010	YES	7:00	YES	19:30	
			30JUN2010	YES	7:30	YES	19:00	
			01JUL2010	YES	8:00	YES	18:00	
			02JUL2010	YES	7:00	YES	18:00	
			03JUL2010	YES	7:30	YES	18:00	
			04JUL2010	YES	7:30	NO		vergessen!
			05JUL2010	YES	7:00	YES	17:30	
			06JUL2010	YES	7:00	YES	17:30	
			07JUL2010	YES	7:00	YES	17:30	
			08JUL2010	YES	8:00	YES	17:30	
			09JUL2010	YES	8:00	YES	18:00	
			10JUL2010	YES	7:00	YES	18:00	
			11JUL2010	YES	7:00	YES	17:30	
			12JUL2010	YES	7:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	13JUL2010	YES	8:00	YES	17:30	
			14JUL2010	YES	8:30	YES	17:30	
			15JUL2010	YES	8:00	YES	18:00	
			16JUL2010	YES	7:00	YES	18:00	
			17JUL2010	YES	7:30	YES	18:00	
			18JUL2010	YES	7:00	YES	18:00	
			19JUL2010	YES	7:00	YES	18:00	
			20JUL2010	YES	8:00	YES	18:00	
			21JUL2010	YES	7:00	YES	17:30	
			22JUL2010	YES	7:30	YES	17:30	
			23JUL2010	YES	8:00	YES	17:30	
			24JUL2010	YES	7:30	YES	17:00	
			25JUL2010	YES	7:30	YES	17:30	
			26JUL2010	YES	7:30	YES	17:30	
			27JUL2010	YES	7:30	YES	17:00	
			28JUL2010	YES	8:00	YES	17:30	
			29JUL2010	YES	7:30	YES	17:30	
			30JUL2010	YES	7:30	YES	17:30	
			31JUL2010	YES	7:30	YES	17:00	
			01AUG2010	YES	8:00	YES	18:00	
			02AUG2010	YES	7:30	YES	17:30	
			03AUG2010	YES	7:00	YES	17:30	
			04AUG2010	YES	7:30	YES	17:30	
			05AUG2010	YES	7:30	YES	17:30	
			06AUG2010	YES	7:30	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	07AUG2010	YES	7:30	YES	17:30	
			08AUG2010	YES	7:30	YES	17:30	
			09AUG2010	YES	7:30	YES	17:30	
			10AUG2010	YES	8:00	YES	18:00	
			11AUG2010	YES	7:00	NO		vergessen!
			12AUG2010	YES	7:30	YES	18:00	
			13AUG2010	YES	7:30	YES	17:30	
			14AUG2010	YES	7:00	YES	17:30	
			15AUG2010	YES	7:30	YES	18:00	
			16AUG2010	YES	7:00	YES	18:00	
			17AUG2010	YES	7:00	YES		
			18AUG2010	YES	7:30	YES	17:30	
			19AUG2010	YES	7:00	YES	18:00	
			20AUG2010	YES	7:30	YES	17:30	
			21AUG2010	YES	7:30	YES	18:00	
			22AUG2010	YES	7:30	YES	17:30	
			23AUG2010	YES	7:30	YES	17:30	
			24AUG2010	YES	8:00	YES	18:00	
			25AUG2010	YES	7:30	YES	18:00	
			26AUG2010	YES	9:00	YES	17:00	
			27AUG2010	YES	7:30	YES	17:30	
			28AUG2010	YES	7:00	NO		vergessen!
			29AUG2010	YES	7:30	YES	18:00	
			30AUG2010	YES	7:30	YES	17:30	
			31AUG2010	YES	7:30	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	01SEP2010	YES	7:30	NO		vergessen
			02SEP2010	YES	7:30	YES	18:00	
			03SEP2010	YES	7:30	YES	17:30	
			04SEP2010	YES	7:30	YES	17:30	
			05SEP2010	YES	7:30	YES	17:00	
			06SEP2010	YES	6:00			
			06SEP2010			YES	18:00	Morgentablette vorheriges Tagebuch
			07SEP2010	YES	8:00	YES	18:00	
			08SEP2010	YES	8:30	YES	18:30	
			09SEP2010	YES	7:00	YES	17:30	
			10SEP2010	YES	7:30	YES	17:00	
			11SEP2010	YES	8:00	YES	18:30	
			12SEP2010	YES	9:00	YES	18:00	
			13SEP2010	YES	8:30	YES	17:30	
			14SEP2010	YES	7:30	YES	19:00	
			15SEP2010	YES	8:00	YES	18:00	
			16SEP2010	YES	7:30	YES	17:30	
			17SEP2010	YES	7:30	YES	17:30	
			18SEP2010	YES	7:30	YES	18:30	
			19SEP2010	YES	8:30	YES	18:00	
			20SEP2010	YES	7:00	YES	18:00	
			21SEP2010	YES	7:30	YES	18:00	
			22SEP2010	YES	8:00	YES	8:00	
			23SEP2010	YES	7:00	YES	18:00	
			24SEP2010	YES	7:30	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	25SEP2010	YES	7:00	YES	17:30	
			26SEP2010	YES	7:00	YES	17:30	
			27SEP2010	YES	8:00	YES	17:30	
			28SEP2010	YES	7:00	YES	17:30	
			29SEP2010	YES	7:30	YES	17:00	
			30SEP2010	YES	7:00	YES	18:00	
			01OCT2010	YES	7:30	YES	18:00	
			02OCT2010	YES	7:00	YES	18:30	
			03OCT2010	YES	8:00	YES	18:00	
			04OCT2010	YES	7:30	YES	18:30	
			05OCT2010	YES	8:00	YES	18:00	
			06OCT2010	YES	9:00	YES	17:30	
			07OCT2010	YES	7:30	YES	17:00	
			08OCT2010	YES	8:00	YES	17:00	
			09OCT2010	YES	7:30	YES	17:30	
			10OCT2010	YES	8:00	YES	18:00	
			11OCT2010	YES	9:00	YES	18:00	
			12OCT2010	YES	8:00	YES	18:00	
			13OCT2010	YES	8:00	YES	20:00	
			14OCT2010	YES	8:00	YES	18:00	
			15OCT2010	YES	7:30	YES	19:00	
			16OCT2010	YES	9:00	YES	19:00	
			17OCT2010	YES	7:30	YES	17:30	
			18OCT2010	YES	8:00	YES	18:00	
			19OCT2010	YES	7:00	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	20OCT2010	YES	7:30	YES	18:00	
			21OCT2010	YES	8:00	YES	18:00	
			22OCT2010	YES	7:30	YES	17:30	
			23OCT2010	YES	8:00	YES	18:00	
			24OCT2010	YES	8:00	YES	19:00	
			25OCT2010	YES	9:00	YES	18:30	
			26OCT2010	YES	9:00	YES	19:00	
			27OCT2010	YES	7:30	YES	22:00	
			28OCT2010	YES	7:30	YES	18:00	
			29OCT2010	YES	7:30	YES	17:30	
			30OCT2010	YES	7:30	YES	18:00	
			31OCT2010	YES	9:00	YES	18:00	
			01NOV2010	YES	8:00	YES	18:00	
			02NOV2010	YES	7:30	YES	18:30	
			03NOV2010	YES	8:30	YES	21:00	
			04NOV2010	YES	9:00	YES	20:00	
			05NOV2010	YES	6:30	YES	18:30	
			06NOV2010	YES	7:30	YES	18:30	
			07NOV2010	YES	8:00	YES	18:30	
			08NOV2010	YES	7:30	YES	18:00	
			09NOV2010	YES	7:30	YES	17:30	
			10NOV2010	YES	8:30	YES	17:30	
			11NOV2010	YES	9:00	YES	18:00	
			12NOV2010	YES	9:00	YES	18:30	
			13NOV2010	YES	8:30	YES	22:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	14NOV2010	YES	8:00	YES	18:30	
			15NOV2010	YES	8:00	YES	18:00	
			16NOV2010	YES	7:30	YES	18:00	
			17NOV2010	YES	8:00	YES	17:30	
			18NOV2010	YES	7:00	YES	17:00	
			19NOV2010	YES	7:30	YES	18:30	
			20NOV2010	YES	7:00	YES	20:30	
			21NOV2010	YES	8:30	YES	21:00	
			22NOV2010	YES	8:30	YES	17:30	
			23NOV2010	YES	8:00	YES	18:30	
			24NOV2010	YES	7:30	YES	19:00	
			25NOV2010	YES	8:00	YES	17:30	
			26NOV2010	YES	8:00	YES	17:30	
			27NOV2010	YES	10:00	YES	17:30	
			28NOV2010	YES	7:30	YES	17:00	
			29NOV2010	YES	8:30	YES	18:00	
			30NOV2010	YES	7:00	YES	17:30	
			01DEC2010	YES	8:00	YES	18:00	
			02DEC2010	YES	7:30	YES	19:30	
			03DEC2010	YES	7:30	YES	18:00	
			04DEC2010	YES	8:30	YES	17:00	
			05DEC2010	YES	8:00	YES	18:00	
			06DEC2010	YES	9:00	YES	18:30	
			07DEC2010	YES	8:30	YES	18:00	
			08DEC2010	YES	8:00	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	045	11	09DEC2010	YES	7:30	YES	17:30	
			10DEC2010	YES	7:00	YES	17:30	
			11DEC2010	YES	8:30	YES	17:00	
			12DEC2010	YES	8:30	YES	18:30	
			13DEC2010	YES	7:30	YES	18:00	
			14DEC2010	YES	8:00	YES	18:00	
			15DEC2010	YES	6:00			
	047	11	04FEB2010	YES	8:00	YES	19:00	
			02AUG2010			YES	18:00	
			03AUG2010	YES	7:00	YES	19:00	
			04AUG2010	YES	7:00	YES	18:00	
			05AUG2010	YES	7:45	YES	19:30	
			06AUG2010	YES	7:00	YES	19:00	
			07AUG2010	YES	7:30	YES	19:00	
			08AUG2010	YES	7:30	YES	18:45	
			09AUG2010	YES	7:30	YES	18:30	
			10AUG2010	YES	7:00	YES	18:30	
			11AUG2010	YES	7:30	YES	18:30	
			12AUG2010	YES	7:00	YES	19:00	
			13AUG2010	YES	7:15	YES	18:30	
			14AUG2010	YES	7:30	YES	19:15	
			15AUG2010	YES	7:45	YES	18:30	
			16AUG2010	YES	7:45	YES	18:30	
			17AUG2010	YES	7:15	YES	19:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	18AUG2010	YES	7:30	YES	18:30	
			19AUG2010	YES	7:45	YES	18:30	
			20AUG2010	YES	7:00	YES	18:30	
			21AUG2010	YES	7:30	YES	19:00	
			22AUG2010	YES	7:30	YES	19:00	
			23AUG2010	YES	7:30	YES	18:00	
			24AUG2010	YES	7:45	YES	18:30	
			25AUG2010	YES	7:45	YES	18:30	
			26AUG2010	YES	7:30	YES	18:30	
			27AUG2010	YES	7:00	YES	18:45	
			28AUG2010	YES	8:00	YES	19:00	
			29AUG2010	YES	8:30	YES	18:45	
			30AUG2010	YES	7:00			
			30AUG2010			YES	18:15	
			31AUG2010	YES	8:00	YES	19:30	
			01SEP2010	YES	8:00	YES	18:30	
			02SEP2010	YES	7:00	YES	19:00	
			03SEP2010	YES	7:30	YES	19:00	
			04SEP2010	YES	7:00	YES	18:45	
			05SEP2010	YES	8:00	YES	18:30	
			06SEP2010	YES	7:30	YES	9:00	
			07SEP2010	YES	7:30	YES	8:00	
			08SEP2010	YES	7:30	YES	18:30	
			09SEP2010	YES	7:45	YES	18:45	
			10SEP2010	YES	7:45	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	11SEP2010	YES	7:30	YES	19:00	
			12SEP2010	YES	7:30	YES	19:30	
			13SEP2010	YES	7:30	YES	20:00	
			14SEP2010	YES	8:00	YES	20:00	
			15SEP2010	YES	8:30	YES	19:15	
			16SEP2010	YES	7:45	YES	21:30	
			17SEP2010	YES	8:00	YES	18:30	
			18SEP2010	YES	8:00	YES	18:15	
			19SEP2010	YES	8:15	YES	19:45	
			20SEP2010	YES	8:00	YES	21:30	
			21SEP2010	YES	8:15	YES	19:00	
			22SEP2010	YES	8:15	YES	22:00	
			23SEP2010	YES	7:45	YES	18:30	
			24SEP2010	YES	7:00	YES	19:00	
			25SEP2010	YES	8:00	YES	19:00	
			26SEP2010	YES	8:00	YES	19:00	
			27SEP2010	YES	8:00	YES	19:00	
			28SEP2010	YES	7:30	YES	18:30	
			29SEP2010	YES	7:30	YES	19:15	
			30SEP2010	YES	7:45	YES	19:00	
			01OCT2010	YES	8:00	YES	18:30	
			02OCT2010	YES	7:45	YES	19:00	
			03OCT2010	YES	8:00	YES	18:30	
			05OCT2010	YES	7:30	YES	20:00	
			06OCT2010	YES	7:30	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	07OCT2010	YES	8:00	YES	18:30	
			08OCT2010	YES	7:30	YES	18:30	
			09OCT2010	YES	8:00	YES	19:00	
			10OCT2010	YES	8:30	YES	19:15	
			11OCT2010	YES	7:45	YES	18:45	
			12OCT2010	YES	7:30	YES	19:00	
			13OCT2010	YES	8:00	YES	20:00	
			14OCT2010	YES	7:30	YES	18:00	
			15OCT2010	YES	7:45	YES	19:00	
			16OCT2010	YES	8:45	YES	19:00	
			17OCT2010	YES	8:45	YES	19:00	
			18OCT2010	YES	8:45	YES	18:30	
			19OCT2010	YES	7:30	YES	20:15	
			20OCT2010	YES	7:30			
			20OCT2010			YES	19:00	
			21OCT2010	YES	7:45	YES	19:15	
			22OCT2010	YES	7:30	YES	20:00	
			23OCT2010	YES	8:00	YES	20:30	
			24OCT2010	YES	8:00	YES	19:00	
			25OCT2010	YES	7:30	YES	18:30	
			26OCT2010	YES	7:30	YES	19:30	
			27OCT2010	YES	7:15	YES	19:00	
			28OCT2010	YES	8:00	YES	20:00	
			29OCT2010	YES	7:30	YES	19:00	
			30OCT2010	YES	7:45	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	31OCT2010	YES	7:30	YES	18:30	
			01NOV2010	YES	8:00	YES	19:45	
			02NOV2010	YES	7:45	YES	20:30	
			03NOV2010	YES	8:00	YES	20:00	
			04NOV2010	YES	7:45	YES	19:00	
			05NOV2010	YES	7:15	YES	18:30	
			06NOV2010	YES	8:00	YES	20:15	
			07NOV2010	YES	8:30	YES	18:30	
			08NOV2010	YES	7:45	YES	19:00	
			09NOV2010	YES	7:30	YES	18:45	
			10NOV2010	YES	8:00	YES	19:00	
			11NOV2010	YES	7:30	YES	19:15	
			12NOV2010	YES	7:30	YES	18:15	
			13NOV2010	YES	8:00	YES	19:15	
			14NOV2010	YES	7:30	YES	20:00	
			15NOV2010	YES	8:00	YES	19:00	
			16NOV2010	YES	7:30	YES	20:00	
			17NOV2010	YES	8:00	YES	18:30	
			18NOV2010	YES	7:45	YES	18:45	
			19NOV2010	YES	7:30	YES	19:00	
			20NOV2010	YES	7:45	YES	19:00	
			21NOV2010	YES	7:30	YES	18:45	
			22NOV2010	YES	8:00	YES	19:00	
			23NOV2010	YES	8:00	YES	19:00	
			24NOV2010	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	25NOV2010	YES	7:30	YES	19:00	
			26NOV2010	YES	7:30	YES	18:30	
			27NOV2010	YES	7:45	YES	19:30	
			28NOV2010	YES	8:15	YES	19:00	
			29NOV2010	YES	7:45	YES	18:15	
			30NOV2010	YES	7:45	YES	20:30	
			01DEC2010	YES	7:30	YES	19:15	
			02DEC2010	YES	7:30	YES	19:15	
			03DEC2010	YES	8:00	YES	18:30	
			04DEC2010	YES	8:00	YES	18:45	
			05DEC2010	YES	8:00	YES	19:00	
			06DEC2010	YES	7:45	YES	18:45	
			07DEC2010	YES	7:30	YES	19:00	
			08DEC2010	YES	8:15	YES	19:15	
			09DEC2010	YES	7:45	YES	19:00	
			10DEC2010	YES	8:00	YES	19:15	
			11DEC2010	YES	8:15	YES	18:45	
			12DEC2010	YES	8:00	YES	18:30	
			13DEC2010	YES	7:45	YES	19:00	
			14DEC2010	YES	8:00	YES	18:30	
			15DEC2010	YES	7:30	YES	18:45	
			16DEC2010	YES	8:00	YES	18:45	
			17DEC2010	YES	8:15	YES	19:15	
			18DEC2010	YES	8:00	YES	19:30	
			19DEC2010	YES	8:30	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	20DEC2010	YES	7:15	YES	20:00	
			21DEC2010	YES	6:45	YES	21:30	
			22DEC2010	YES	8:00	YES	19:30	
			23DEC2010	YES	8:15	YES	19:15	
			24DEC2010	YES	8:30	YES	19:00	
			25DEC2010	YES	8:00	YES	19:00	
			26DEC2010	YES	8:00	YES	19:00	
			27DEC2010	YES	8:00	YES	19:30	
			28DEC2010	YES	8:00	YES	20:00	
			29DEC2010	YES	8:15	YES	19:00	
			30DEC2010	YES	8:00	YES	18:45	
			31DEC2010	YES	9:30	YES	19:30	
			01JAN2011	YES	9:00	YES	18:45	
			02JAN2011	YES	8:00	YES	18:45	
			03JAN2011	YES	8:00	YES	19:00	
			04JAN2011	YES	7:30	YES	18:30	
			05JAN2011	YES	7:30	YES	19:30	
			06JAN2011	YES	8:00	YES		
			07JAN2011	YES		YES		
			08JAN2011	YES	7:45	YES	19:15	
			09JAN2011	YES	7:30	YES	19:00	
			10JAN2011	YES	7:30			
			10JAN2011			YES	19:00	
			11JAN2011	YES	7:30	YES	20:30	
			12JAN2011	YES	7:45	YES	21:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	13JAN2011	YES	7:30	YES	18:30	
			14JAN2011	YES	7:45	YES	18:45	
			15JAN2011	YES	8:00	YES	19:30	
			16JAN2011	YES	7:45	YES	19:00	
			17JAN2011	YES	7:30	YES	18:30	
			18JAN2011	YES	8:00	YES	19:15	
			19JAN2011	YES	7:45	YES	19:30	
			20JAN2011	YES	8:00	YES	18:30	
			21JAN2011	YES	8:15	YES	19:15	
			22JAN2011	YES	8:00	YES	19:00	
			23JAN2011	YES	8:45	YES	19:15	
			24JAN2011	YES	8:30	YES	19:00	
			25JAN2011	YES	8:00	YES	18:45	
			26JAN2011	YES	8:30	YES	19:15	
			27JAN2011	YES	8:15	YES	19:00	
			28JAN2011	YES	8:00	YES	18:30	
			29JAN2011	YES	7:00	YES	19:00	
			30JAN2011	YES	7:30	YES	20:00	
			31JAN2011	YES	8:00	YES	18:30	
			01FEB2011	YES	8:00	YES	18:45	
			02FEB2011	YES	7:30	YES	19:00	
			03FEB2011	YES	7:45	YES	18:30	
			04FEB2011	YES	8:00	YES	19:00	
			05FEB2011	YES	7:30	YES	19:15	
			06FEB2011	YES	8:00	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	07FEB2011	YES	7:30	YES	19:00	
			08FEB2011	YES	7:45	YES	20:30	
			09FEB2011	YES	8:15	YES	20:15	
			10FEB2011	YES	8:00	YES	19:15	
			11FEB2011	YES	7:45	YES	19:00	
			12FEB2011	YES	8:15	YES	19:30	
			13FEB2011	YES	7:45	YES	18:30	
			14FEB2011	YES	8:00	YES	18:45	
			15FEB2011	YES	7:30	YES	19:30	
			16FEB2011	YES	7:45	YES	18:30	
			17FEB2011	YES	8:00	YES	18:45	
			18FEB2011	YES	7:30	YES	18:30	
			19FEB2011	YES	8:00	YES	19:00	
			20FEB2011	YES	8:15	YES	18:45	
			21FEB2011	YES	7:00	YES	18:30	
			22FEB2011	YES	7:30	YES	18:30	
			23FEB2011	YES	8:00	YES	19:00	
			24FEB2011	YES	7:15	YES	19:00	
			25FEB2011	YES	7:30	YES	20:15	
			26FEB2011	YES	8:15	YES	19:00	
			27FEB2011	YES	7:45	YES	18:45	
			28FEB2011	YES	7:30	YES	18:30	
			01MAR2011	YES	7:45	YES	19:15	
			02MAR2011	YES	8:00	YES	19:30	
			03MAR2011	YES	8:15	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	04MAR2011	YES	7:45	YES	19:00	
			05MAR2011	YES	7:30	YES	19:30	
			06MAR2011	YES	7:45	YES	19:00	
			07MAR2011	YES	7:30	YES	20:15	
			08MAR2011	YES	7:30	YES	18:30	
			09MAR2011	YES	7:15	YES	18:45	
			10MAR2011	YES	7:15	YES	18:30	
			11MAR2011	YES	7:45	YES	18:15	
			12MAR2011	YES	7:30	YES	18:45	
			13MAR2011	YES	7:45	YES	19:15	
			14MAR2011	YES	7:30	YES	19:00	
			15MAR2011	YES	7:45	YES	19:30	
			16MAR2011	YES	8:00	YES	19:00	
			17MAR2011	YES	7:45	YES	19:15	
			18MAR2011	YES	8:00	YES	19:00	
			19MAR2011	YES	7:30	YES	18:45	
			20MAR2011	YES	7:45	YES	18:30	
			21MAR2011	YES	7:30	YES	18:45	
			22MAR2011	YES	7:30	YES	20:00	
			23MAR2011	YES	7:30	YES	18:30	
			24MAR2011	YES	7:45	YES	18:45	
			25MAR2011	YES	8:00	YES	18:30	
			26MAR2011	YES	7:45	YES	19:00	
			27MAR2011	YES	7:30	YES	19:00	
			28MAR2011	YES	7:15	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	29MAR2011	YES	7:45	YES	19:30	
			30MAR2011	YES	7:30	YES	18:30	
			31MAR2011	YES	8:00	YES	19:00	
			01APR2011	YES	7:30	YES	18:30	
			02APR2011	YES	7:45	YES	19:00	
			03APR2011	YES	7:30	YES	19:15	
			04APR2011	YES	7:30	YES	19:30	
			05APR2011	YES	8:15	YES	18:30	
			06APR2011	YES	7:30	YES	19:00	
			07APR2011	YES	8:00	YES	18:30	
			08APR2011	YES	7:15	YES	19:00	
			09APR2011	YES	7:00	YES	18:30	
			10APR2011	YES	7:30	YES	18:45	
			11APR2011	YES	8:00	YES	19:00	
			12APR2011	YES	7:30			
			12APR2011			YES	19:00	
			13APR2011	YES	8:00	YES	18:30	
			14APR2011	YES	7:15	YES	18:45	
			15APR2011	YES	7:45	YES	19:00	
			16APR2011	YES	8:15	YES	18:45	
			17APR2011	YES	8:00	YES	18:30	
			18APR2011	YES	7:45	YES	18:45	
			19APR2011	YES	7:30	YES	19:00	
			20APR2011	YES	7:45	YES	19:15	
			21APR2011	YES	8:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	22APR2011	YES	8:15	YES	19:15	
			23APR2011	YES	7:30	YES	18:45	
			24APR2011	YES	7:45	YES	19:00	
			25APR2011	YES	7:15	YES	18:30	
			26APR2011	YES	7:30	YES	19:30	
			27APR2011	YES	7:45	YES	19:15	
			28APR2011	YES	8:00	YES	19:45	
			29APR2011	YES	7:30	YES	19:00	
			30APR2011	YES	7:30	YES	19:15	
			01MAY2011	YES	8:00	YES	18:30	
			02MAY2011	YES	7:45	YES	18:45	
			03MAY2011	YES	7:30	YES	19:00	
			04MAY2011	YES	7:45	YES	20:30	
			05MAY2011	YES	8:30	YES	18:30	
			06MAY2011	YES	7:15	YES	19:00	
			07MAY2011	YES	7:30	YES	18:30	
			08MAY2011	YES	7:15	YES	18:45	
			09MAY2011	YES	7:00	YES	18:00	
			10MAY2011	YES	7:30	YES	18:45	
			11MAY2011	YES	7:45	YES	19:00	
			12MAY2011	YES	7:30	YES	18:00	
			13MAY2011	YES	7:45	YES	18:30	
			14MAY2011	YES	8:00	YES	19:00	
			15MAY2011	YES	7:15	YES	19:15	
			16MAY2011	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	17MAY2011	YES	7:00	YES	19:00	
			18MAY2011	YES	7:30	YES	19:00	
			19MAY2011	YES	7:45	YES	19:15	
			20MAY2011	YES	7:30	YES	19:15	
			21MAY2011	YES	7:45	YES	18:30	
			22MAY2011	YES	7:30	YES	19:00	
			23MAY2011	YES	8:00	YES	18:30	
			24MAY2011	YES	7:30	YES	19:00	
			25MAY2011	YES	7:15	YES	19:15	
			26MAY2011	YES	7:15	YES	19:30	
			27MAY2011	YES	7:30	YES	19:00	
			28MAY2011	YES	7:30	YES	19:00	
			29MAY2011	YES	7:45	YES	19:30	
			30MAY2011	YES	8:00	YES	19:45	
			31MAY2011	YES	7:45	YES	19:00	
			01JUN2011	YES	7:30	YES	18:45	
			02JUN2011	YES	8:00	YES	19:00	
			03JUN2011	YES	7:30	YES	18:30	
			04JUN2011	YES	7:45	YES	19:00	
			05JUN2011	YES	8:00	YES	19:00	
			06JUN2011	YES	7:30	YES	18:30	
			07JUN2011	YES	7:45	YES	18:45	
			08JUN2011	YES	7:30	YES	19:00	
			09JUN2011	YES	7:00	YES	20:00	
			10JUN2011	YES	8:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	11JUN2011	YES	8:00	YES	19:30	
			12JUN2011	YES	8:15	YES	19:00	
			13JUN2011	YES	8:00	YES	19:45	
			14JUN2011	YES	8:45	YES	19:00	
			15JUN2011	YES	8:45	YES	20:00	
			16JUN2011	YES	8:00	YES	18:30	
			17JUN2011	YES	7:45	YES	18:30	
			18JUN2011	YES	8:30	YES	19:00	
			19JUN2011	YES	8:30	YES	18:45	
			20JUN2011	YES	8:00	YES	19:45	
			21JUN2011	YES	7:15	YES	21:00	
			22JUN2011	YES	8:00	YES	19:00	
			23JUN2011	YES	8:00	YES	18:45	
			24JUN2011	YES	7:30	YES	19:00	
			25JUN2011	YES	7:15	YES	18:45	
			26JUN2011	YES	7:45	YES	19:00	
			27JUN2011	YES	8:00	YES	19:15	
			28JUN2011	YES	7:30	YES	19:00	
			29JUN2011	YES	7:45	YES	19:15	
			30JUN2011	YES	7:30	YES	19:00	
			01JUL2011	YES	7:15	YES	19:00	
			02JUL2011	YES	7:30	YES	19:00	
			03JUL2011	YES	7:30	YES	20:00	
			04JUL2011	YES	7:00	YES	19:00	
			05JUL2011	YES	7:30	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	047	11	06JUL2011	YES	7:15	YES	18:30	
			07JUL2011	YES	7:45	YES	19:00	
			08JUL2011	YES	8:00	YES	18:45	
			09JUL2011	YES	6:45	YES	20:30	
			10JUL2011	YES	7:45	YES	18:30	
			11JUL2011	YES	7:30	YES	19:30	
			12JUL2011	YES	7:00	YES	19:00	
			13JUL2011	YES	7:15	YES	19:00	
			14JUL2011	YES	7:30	YES	18:45	
			15JUL2011	YES	7:30	YES	18:45	
			16JUL2011	YES	7:45	YES	19:00	
			17JUL2011	YES	8:00	YES	18:30	
			18JUL2011	YES	7:30	YES	19:00	
			19JUL2011	YES	7:00	YES	19:30	
			20JUL2011	YES	7:30	YES	19:30	
			21JUL2011	YES	7:30	YES	19:00	
			22JUL2011	YES	7:00	YES	18:30	
			23JUL2011	YES	7:30	YES	19:30	
			24JUL2011	YES	7:45	YES	19:00	
			25JUL2011	YES	7:30	YES	19:15	
			26JUL2011	YES	8:00	YES	20:00	
			27JUL2011	YES	6:30			
	049	21	28OCT2010	YES	7:00	YES	18:30	
			29OCT2010	YES	6:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	30OCT2010	YES	6:00	NO		Abends abwesend
			31OCT2010	YES	7:30	YES	17:45	
			01NOV2010	YES	8:00	YES	18:00	Anfall
			02NOV2010	YES	8:30	YES	19:30	Anfall
			03NOV2010	YES	7:00	YES	22:00	Zu spät, Anfall nach dem Essen
			04NOV2010	YES	7:00	YES	18:30	Anfall
			05NOV2010	YES	7:30	YES	18:30	
			06NOV2010	YES	7:30	YES	18:30	
			07NOV2010	YES	7:00	YES	18:30	
			08NOV2010	YES	7:30	YES	18:30	Anfall
			09NOV2010	YES	7:00	YES	18:00	
			10NOV2010	YES	7:00	YES	18:00	
			11NOV2010	YES	7:30	YES	18:00	
			12NOV2010	YES	8:00		18:00	
			13NOV2010	YES	7:00	YES	18:00	
			14NOV2010	YES	5:00	YES	22:00	Ohne Essen
			15NOV2010	YES	7:00	YES	18:30	
			16NOV2010	YES	7:00	YES	20:00	
			17NOV2010	YES	7:30	YES	17:30	
			18NOV2010	YES	7:30	YES	18:00	
			19NOV2010	YES	7:30	YES	18:00	
			20NOV2010	YES	7:00	YES	18:30	
			21NOV2010	YES	7:30	YES	17:30	
			22NOV2010	YES	6:00			
			22NOV2010			YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	23NOV2010	YES	6:30	YES	18:00	
			24NOV2010	YES	6:30	YES	18:30	
			25NOV2010	YES	6:30	YES	18:00	
			26NOV2010	YES	6:30	YES	18:30	
			27NOV2010	YES	7:00	YES	17:30	
			28NOV2010	YES	6:00	YES	18:00	
			29NOV2010	YES	6:00	YES	17:45	
			30NOV2010	YES	7:00	YES	17:00	
			01DEC2010	YES	6:00	YES	18:00	
			02DEC2010	YES	7:00	YES	18:30	
			03DEC2010	YES	7:00	YES	18:30	
			04DEC2010	YES	8:00	YES	18:30	
			05DEC2010	YES	5:30	YES	18:30	
			06DEC2010	YES	6:00	YES	18:15	
			07DEC2010	YES	7:00	YES	17:30	
			08DEC2010	YES	7:30	YES	18:00	
			09DEC2010	YES	7:00	YES	17:30	
			10DEC2010	YES	7:00	YES	18:00	
			11DEC2010	YES	7:00	YES	18:00	
			12DEC2010	YES	6:00	YES	22:00	
			13DEC2010	YES	7:00	YES	19:30	
			14DEC2010	YES	6:00	YES	19:00	
			15DEC2010	YES	7:30	YES	18:30	
			16DEC2010	YES	7:00	YES	18:00	
			17DEC2010	YES	6:00		19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	18DEC2010	YES	9:00	YES	19:30	2 x 1/2 St. Ausfälle
			19DEC2010	YES	6:00	YES	17:30	
			20DEC2010	YES	6:00	YES	17:30	
			21DEC2010	YES	7:30	YES	18:00	
			22DEC2010	YES	7:00	YES	19:30	
			23DEC2010	YES	7:00	YES	18:00	
			24DEC2010	YES	7:00	YES	17:00	
			25DEC2010	YES	6:00	YES	18:00	
			26DEC2010	YES	7:00	YES	17:00	
			27DEC2010	YES	6:00	YES	18:00	
			28DEC2010	YES	7:00	YES	18:00	
			29DEC2010	YES	7:00	YES	18:00	
			30DEC2010	YES	7:00	YES	18:30	
			31DEC2010	YES	7:30	YES	18:00	
			01JAN2011	YES	7:00	YES	18:00	
			02JAN2011	YES	8:00	YES	17:30	
			03JAN2011	YES	7:30	YES	18:00	
			04JAN2011	YES	5:30	YES	18:00	
			05JAN2011	YES	7:00	YES	18:00	
			06JAN2011	YES	6:00	YES	18:00	
			07JAN2011	YES	7:00	YES	17:30	
			08JAN2011	YES	7:30	YES	19:00	
			09JAN2011	YES	7:00	YES	18:00	
			10JAN2011	YES	7:30		18:00	
			11JAN2011	YES	8:00	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	12JAN2011	YES	7:00	YES	19:00	
			13JAN2011	YES	7:30		17:00	Heute abend Anfall
			14JAN2011	YES	8:00	YES	20:00	
			15JAN2011	YES	6:30	YES	18:00	
			16JAN2011	YES	7:00		18:00	
			17JAN2011	YES	7:30		18:30	
			18JAN2011	YES	6:30			
			18JAN2011			YES	18:00	
			19JAN2011	YES	7:30	YES	17:00	
			20JAN2011	YES	6:00	YES	18:30	
			21JAN2011		7:00	YES	19:00	
			22JAN2011	YES	7:00	YES	18:00	
			23JAN2011	YES	7:30	YES	18:00	
			24JAN2011	YES	8:00	YES	18:00	
			25JAN2011	YES	7:00		19:15	
			26JAN2011	YES	7:00	YES	17:00	Anfall wegen 10 Tabletten 16:00 - 21:00
			27JAN2011	YES	6:30	YES	18:00	
			28JAN2011	YES	8:00	YES	17:00	
			29JAN2011	YES	7:30	YES	19:00	
			30JAN2011	YES	7:30	YES	18:00	P heute etwas verkühlt mit Husten, abends 1 Aspro gegeben
			31JAN2011	YES	7:30	YES	18:00	
			01FEB2011	YES	8:00	YES	18:00	
			02FEB2011	YES	8:00	YES	19:00	
			03FEB2011	YES	7:30	YES	17:00	Unausstehlich

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	04FEB2011	YES	7:00	YES	17:30	Durchgedreht?
			05FEB2011	YES	7:30	YES	18:00	Gleich!
			06FEB2011	YES	7:00	YES	18:00	Gleich! Erste Besserung
			07FEB2011	YES	7:30	YES	18:00	
			08FEB2011	YES	8:00	YES	18:30	
			09FEB2011	YES	7:30	YES	18:00	
			10FEB2011	YES	7:00	YES	20:00	
			11FEB2011	YES	7:30	YES	18:00	Abends will nicht weggehen, gehe allein ver cin?
			12FEB2011	YES	7:00	YES	18:00	
			13FEB2011	YES	6:30	YES	18:30	
			14FEB2011	YES	8:00	YES	18:00	
			15FEB2011	YES	7:30	YES	17:00	
			16FEB2011	YES	6:00	YES	18:00	
			17FEB2011	YES	8:00	YES	17:30	
			18FEB2011	YES	6:30	YES	17:30	
			19FEB2011	YES	5:30	YES	18:30	
			20FEB2011	YES	7:30	YES	19:00	
			21FEB2011	YES	7:30	YES	18:30	
			22FEB2011	YES	5:30	YES	18:00	
			23FEB2011		7:30	YES	17:30	
			24FEB2011	YES	8:00	YES	18:00	
			25FEB2011	YES	7:30	YES	18:00	
			26FEB2011	YES	8:00	YES	18:00	
			27FEB2011	YES	7:30	YES	18:00	Will nicht fortgehen, Türe fliegen
			28FEB2011	YES	7:30	YES	19:00	Nach Protest mit mir einkaufen

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	01MAR2011	YES	8:00	YES	18:00	
			02MAR2011	YES	8:00	YES	18:00	
			03MAR2011	YES	7:30	YES	18:00	
			04MAR2011	YES	6:30	YES	18:30	
			05MAR2011	YES	7:00	YES	18:00	
			06MAR2011	YES	7:00	YES	18:00	
			07MAR2011	YES	7:00	YES	18:00	
			08MAR2011	YES	8:00	YES	21:00	
			09MAR2011	YES	7:30	YES	18:00	
			10MAR2011	YES	8:00	YES	17:30	
			11MAR2011	YES	7:00	YES	18:00	
			12MAR2011	YES	7:15		18:00	Verweigerung zum mitgehen, Türen schlagen, MS war
			13MAR2011	YES	7:30	YES	18:00	
			14MAR2011	YES	8:00	YES	18:00	
			15MAR2011	YES	7:30	YES	18:00	
			16MAR2011	YES	7:00	YES	18:30	
			17MAR2011	YES	7:30	YES	18:00	
			18MAR2011	YES	8:00	YES	18:30	Will nicht weggehen u. essen, ist einfach verrückt
			19MAR2011	YES	8:00	YES	18:00	Gleich
			20MAR2011	YES	7:00	YES	19:00	
			21MAR2011	YES	8:00	YES	18:00	
			22MAR2011	YES	7:30	YES	17:00	
			23MAR2011	YES	7:30	YES	18:00	
			24MAR2011	YES	8:00	YES	17:30	
			25MAR2011	YES	7:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	26MAR2011	YES	7:00	YES	19:00	
			27MAR2011	YES	6:00	YES	18:00	
			28MAR2011	YES	8:00	YES	17:30	
			29MAR2011	YES	8:00	YES	17:30	
			30MAR2011	YES	7:30	YES	18:00	
			31MAR2011	YES	8:00	YES	18:00	
			01APR2011	YES	8:00	YES	17:30	
			02APR2011	YES	7:30	YES	18:00	
			03APR2011	YES	5:30	YES	18:00	
			04APR2011	YES	6:00	YES	17:00	
			05APR2011	YES	5:30	YES	17:30	
			06APR2011	YES	6:00	YES	18:00	
			07APR2011	YES	6:00	YES	18:00	
			08APR2011	YES	7:00	YES	19:00	
			09APR2011	YES	8:00	YES	18:00	
			10APR2011	YES	8:00	YES	18:00	
			11APR2011	YES	7:30	YES	17:30	
			12APR2011	YES	5:30			
			12APR2011			YES	18:00	
			13APR2011	YES	7:00		18:00	
			15APR2011	YES	7:30	YES	18:00	
			16APR2011	YES	7:00	YES	18:00	
			17APR2011	YES	5:30	YES	18:30	
			18APR2011	YES	7:00	YES	17:30	
			19APR2011	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	20APR2011	YES	7:00	YES	18:00	
			21APR2011	YES	7:30	YES	18:30	
			22APR2011	YES	7:30	YES	17:30	
			23APR2011	YES	7:00	YES	17:30	
			24APR2011	YES	5:00	YES	17:00	
			25APR2011	YES	7:00	YES	17:00	
			26APR2011	YES	7:00	YES	16:30	
			27APR2011	YES	5:30	YES	17:00	
			28APR2011	YES	7:30	YES	16:00	
			29APR2011	YES	7:00	YES	18:30	
			30APR2011	YES	7:00	YES	18:00	
			01MAY2011	YES	8:00	YES	18:00	
			02MAY2011	YES	7:30	YES	18:30	
			03MAY2011	YES	8:00	YES	18:30	
			04MAY2011	YES	5:30	YES	19:00	
			05MAY2011	YES	6:30	YES	19:00	
			06MAY2011	YES	6:30	YES	19:00	
			07MAY2011	YES	6:30	YES	19:00	
			08MAY2011	YES	7:00	YES	20:30	Früh schlecht erbrochen, ganzen Tag mehr apathisch
			09MAY2011	YES	7:00	YES	18:00	Ganzen Tag teils apathisch, abends gleich ins Bett
			10MAY2011	YES	8:00	YES	20:00	
			11MAY2011	YES	7:00	YES	18:00	
			12MAY2011	YES	7:30	YES	18:00	
			13MAY2011	YES	7:00	YES	18:30	
			14MAY2011	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	15MAY2011	YES	7:30	YES	18:00	
			16MAY2011	YES	7:00	YES	18:00	
			17MAY2011	YES	8:00	YES	18:30	
			18MAY2011	YES	7:30	YES	18:00	
			19MAY2011	YES	7:30	YES	17:00	
			20MAY2011	YES	7:00	YES	17:30	
			21MAY2011	YES	8:00	YES	18:00	
			22MAY2011	YES	7:30	YES	17:00	
			23MAY2011	YES	7:30	YES	17:00	
			24MAY2011	YES	7:00	YES	17:30	
			25MAY2011	YES	7:00	YES	17:30	
			26MAY2011	YES	7:30	YES	17:00	
			27MAY2011	YES	7:00	YES	18:00	
			28MAY2011	YES	8:00	YES	18:00	
			29MAY2011	YES	6:00	YES	18:00	
			30MAY2011	YES	7:00	YES	18:30	
			31MAY2011	YES	6:00	YES	18:00	
			01JUN2011	YES	8:00	YES	18:30	
			02JUN2011	YES	7:00	YES	17:30	
			03JUN2011	YES	7:30	YES	18:00	
			04JUN2011	YES	6:00	YES	18:00	
			05JUN2011	YES	7:00	YES	18:00	
			06JUN2011	YES	7:00	YES	17:30	
			07JUN2011	YES	7:30	YES	18:30	
			08JUN2011	YES	8:00	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	09JUN2011	YES	7:30	YES	19:00	
			10JUN2011	YES	5:00	YES	18:00	
			11JUN2011	YES	7:30		18:00	
			12JUN2011	YES	7:00	YES	18:30	
			13JUN2011	YES	8:00	YES	19:00	
			14JUN2011	YES	7:00	YES	18:30	
			15JUN2011	YES	7:00	YES	18:00	
			16JUN2011	YES	6:30		18:00	
			17JUN2011	YES	7:00	YES	17:30	
			18JUN2011	YES	7:00	YES	17:00	
			19JUN2011	YES	7:00	YES	17:30	
			20JUN2011	YES	7:30	YES	17:30	
			21JUN2011	YES	6:30	YES	17:00	
			22JUN2011	YES	7:00	YES	18:00	
			23JUN2011	YES	7:30	YES	18:00	
			24JUN2011	YES	6:30	YES	19:00	
			25JUN2011	YES	7:30	YES	18:30	
			26JUN2011	YES	7:30	YES	18:30	
			27JUN2011	YES	5:00	YES	18:30	
			28JUN2011	YES	7:30	YES	19:00	
			29JUN2011	YES	7:30	YES	19:00	
			30JUN2011	YES	7:30	YES	19:00	
			01JUL2011	YES	7:30	YES	19:00	
			02JUL2011	YES	7:30	YES	19:00	
			03JUL2011	YES	5:00	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	04JUL2011	YES	6:30			
			05JUL2011			YES	19:00	
			06JUL2011	YES	7:00	YES	18:00	
			07JUL2011	YES	7:15	YES	18:00	
			08JUL2011	YES	6:30	YES	18:30	
			09JUL2011	YES	7:00	YES	18:00	
			10JUL2011	YES	7:30	YES	17:30	
			11JUL2011	YES	6:00	YES	18:00	
			12JUL2011	YES	7:00	YES	19:00	
			13JUL2011	YES	7:30	YES	18:00	
			14JUL2011	YES	7:00	YES	18:00	
			15JUL2011	YES	7:30	YES	18:00	
			16JUL2011	YES	6:30	YES	18:30	
			17JUL2011	YES	7:00	YES	18:30	
			18JUL2011	YES	7:30	YES	18:00	
			19JUL2011	YES	6:30	YES	18:30	
			20JUL2011	YES	7:00	YES	18:00	
			21JUL2011	YES	8:00		19:00	
			22JUL2011	YES	8:00	YES	18:30	
			23JUL2011	YES	7:30	YES	19:00	
			24JUL2011	YES	7:00	YES	18:00	
			25JUL2011	YES	5:00	YES	18:00	
			26JUL2011	YES	7:00	YES	18:00	
			27JUL2011	YES	7:15	YES	18:30	
			28JUL2011	YES	7:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	29JUL2011	YES	7:30	YES	18:30	
			30JUL2011	YES	7:00	YES	18:00	
			31JUL2011	YES	7:00	YES	18:00	
			01AUG2011	YES	6:00	YES	19:00	
			02AUG2011	YES	7:00	YES	17:00	
			03AUG2011	YES	7:30	YES	18:00	
			04AUG2011	YES	7:30	YES	18:00	
			05AUG2011	YES	8:00	YES	19:00	
			06AUG2011	YES	7:30	YES	18:30	
			07AUG2011	YES	7:00	YES	18:00	
			08AUG2011	YES	7:45	YES	18:00	
			09AUG2011	YES	8:00	YES	19:00	
			10AUG2011	YES	7:30	YES	18:00	
			11AUG2011	YES	8:00	YES	19:00	
			12AUG2011	YES	7:00	YES	18:00	
			13AUG2011	YES	7:00	YES	17:30	
			14AUG2011	YES	7:30	YES	18:00	
			15AUG2011	YES	7:00	YES	18:00	
			16AUG2011	YES	7:30	YES	18:00	
			17AUG2011	YES	8:00	YES	18:30	
			18AUG2011	YES	7:30	YES	17:30	
			19AUG2011	YES	6:30		19:00	
			20AUG2011	YES	6:30		19:00	
			21AUG2011	YES	8:00	YES	17:30	
			22AUG2011	YES	7:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	049	21	23AUG2011	YES	7:30	YES	18:00	
			24AUG2011	YES	8:00	YES	18:30	
			25AUG2011	YES	8:00	YES	17:30	
			26AUG2011	YES	7:30	YES	17:30	
			27AUG2011	YES	7:30	YES	17:00	
			28AUG2011	YES	6:30	YES	18:00	
			29AUG2011	YES	7:30	YES	18:00	
			30AUG2011	YES	8:00	YES	19:00	
			31AUG2011	YES	7:30	YES	19:00	
			01SEP2011	YES	7:30	YES	18:00	fast nichts nun Toilette
			02SEP2011	YES	7:30	YES	17:45	fast nichts
			03SEP2011	YES	8:00	YES	18:00	kein Essen
			04SEP2011	YES	6:00	YES	18:30	kein Essen
			05SEP2011	YES	8:00	YES	18:00	kein Essen
			06SEP2011	YES	7:00			
	051	21	28OCT2010			YES	18:30	
			29OCT2010	YES	7:50	YES	18:20	
			30OCT2010	YES	8:35	YES	19:20	
			31OCT2010	YES	8:30	YES	17:46	
			01NOV2010	YES	8:20	YES	17:15	
			02NOV2010	YES	7:40			
			03NOV2010	YES	8:30	YES	18:30	
			04NOV2010	YES	7:35	YES	17:20	
			05NOV2010	YES	7:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	06NOV2010	YES	7:35	YES	17:20	
			07NOV2010	YES	8:20	YES	19:05	nach Abendessen, da wir eingeladen waren
			08NOV2010	YES	7:05		16:50	
			09NOV2010	YES	7:30		17:00	
			10NOV2010	YES	7:05	YES	17:00	
			11NOV2010	YES	8:10		17:30	
			12NOV2010	YES	7:55	YES	17:30	
			13NOV2010	YES	8:30	YES	17:15	
			14NOV2010	YES	8:00	YES	17:00	
			15NOV2010	YES	6:45	YES	17:00	
			16NOV2010	YES	7:40	YES	17:45	
			17NOV2010	YES	7:45	YES	17:15	
			18NOV2010	YES	7:40	YES	17:10	
			19NOV2010		8:30	YES	17:30	
			20NOV2010	YES	9:00	YES	17:30	
			21NOV2010	YES	7:35	YES	17:10	
			22NOV2010	YES	7:20	YES	16:50	
			23NOV2010		6:30			
			23NOV2010	YES	6:50	YES	17:30	
			24NOV2010	YES	6:50	YES		
			25NOV2010		7:00		17:10	
			26NOV2010		6:10		16:50	
			27NOV2010		7:50	YES	19:30	Leider nach Abendessen, da Einladung
			28NOV2010		7:50	YES	18:30	
			29NOV2010	YES	6:30	YES	9:00	Nachher, da Besuch

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	30NOV2010	YES	7:05	YES	16:50	
			01DEC2010	YES	6:15		17:40	
			02DEC2010	YES				
			03DEC2010	YES	6:45	YES	20:00	
			04DEC2010	YES	8:20	YES	19:30	
			05DEC2010	YES	7:45		20:30	Einladung
			06DEC2010	YES	7:30	YES	17:10	
			07DEC2010	YES	7:10	YES	19:15	
			08DEC2010	YES	8:35	YES	17:30	
			09DEC2010	YES	7:55	YES	17:45	
			10DEC2010	YES	6:55	YES	17:45	
			11DEC2010	YES	8:20	YES	19:15	
			12DEC2010	YES	9:30	YES	17:05	
			14DEC2010		7:30		17:00	
			15DEC2010		7:20		18:00	
			16DEC2010	YES	7:00		18:45	
			17DEC2010	YES	6:00	YES	19:45	
			18DEC2010	YES	8:30	YES	17:30	
			19DEC2010		6:55	YES	17:50	
			21DEC2010		6:00	YES	17:35	
			23DEC2010	YES	7:15	YES	17:50	
			24DEC2010	YES	8:30	YES	16:00	
			25DEC2010	YES	8:45	YES	16:50	
			26DEC2010	YES	8:50		17:50	
			27DEC2010	YES	6:50	YES	16:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	28DEC2010	YES	5:50			
			30DEC2010	YES	7:30		17:50	
			31DEC2010	YES	8:50	YES		
			01JAN2011	YES	10:00	YES	18:00	Nach Frühstück
			02JAN2011	YES	9:00			
			03JAN2011	YES	7:30	YES	17:15	
			04JAN2011	YES	6:50	YES	17:30	
			05JAN2011		7:15		17:25	
			06JAN2011	YES	9:00			Nach Frühstück (Verschlafen)
			07JAN2011	YES	7:00	YES	17:10	
			08JAN2011	YES	8:30		17:20	
			09JAN2011	YES	8:25	YES	17:20	
			10JAN2011	YES	7:25	YES	18:00	
			11JAN2011	YES	7:30		17:30	
			12JAN2011		6:30		18:30	
			13JAN2011		6:30	YES	18:00	hat Tabletten von selbst genommen!
			14JAN2011	YES	6:30	YES	17:20	
			15JAN2011	YES	7:00	YES	19:20	
			16JAN2011	YES	9:05	YES	18:00	
			17JAN2011	YES	7:00	YES	18:05	
			18JAN2011	YES	6:45	YES	17:15	
			19JAN2011	YES	6:30	YES	18:00	
			20JAN2011	YES	7:00	YES	18:10	
			21JAN2011	YES	7:10	YES	17:20	
			22JAN2011	YES	7:30	YES	18:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	23JAN2011	YES	7:30	YES	18:00	
			24JAN2011	YES	7:00	YES	17:55	
			25JAN2011		7:10	YES	18:00	
			26JAN2011	YES	7:20	YES	17:10	
			27JAN2011	YES	7:20	YES	17:40	
			28JAN2011	YES	7:25	YES	17:40	
			29JAN2011	YES	7:45	YES	18:15	
			30JAN2011	YES	7:45	YES	17:35	selber genommen
			31JAN2011	YES	7:00	YES	16:55	
			01FEB2011			YES	17:15	In der Früh um 06:50 h (Kliniktermin)
			02FEB2011	YES	7:05	YES	18:00	selber genommen
			03FEB2011	YES	5:30			
			04FEB2011	YES	7:00	YES	18:00	
			05FEB2011	YES	8:45	YES	17:00	
			06FEB2011	YES	9:15	YES	18:00	
			07FEB2011	YES	6:45	YES	17:20	
			08FEB2011	YES	7:10	YES	18:00	
			09FEB2011	YES	7:30	YES	17:20	
			10FEB2011	YES	7:15	YES	17:50	
			11FEB2011		6:30	YES	18:00	
			12FEB2011	YES	8:30	YES	17:20	
			13FEB2011	YES	8:45	YES	16:45	
			14FEB2011	YES	7:15	YES	18:00	
			15FEB2011	YES	7:30	YES	17:55	
			16FEB2011	YES	7:30	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	17FEB2011	YES	7:15	YES	17:00	
			18FEB2011	YES	7:30	YES	17:30	
			19FEB2011	YES	8:30	YES	17:00	
			20FEB2011	YES	9:30	YES	17:00	
			21FEB2011	YES	7:30	YES	17:30	
			22FEB2011	YES	7:15	YES	17:50	
			23FEB2011	YES	7:30	YES	19:00	
			24FEB2011	YES	7:20	YES	18:00	
			25FEB2011	YES	7:25	YES	17:30	
			26FEB2011	YES	8:00	YES	18:10	
			27FEB2011	YES	8:30	YES	18:30	
			28FEB2011	YES	7:45	YES	18:30	Nach Essen (davor Einladung)
			01MAR2011	YES	6:50	YES	17:30	
			02MAR2011		7:20	YES	17:50	
			03MAR2011	YES	7:15	YES	16:30	von 02.03.2011 auf 03.03.2011 in d.Nacht Beklemmungen + Angstzustände
			04MAR2011	YES	7:00	YES	17:00	
			05MAR2011	YES	8:15	YES	17:30	
			06MAR2011	YES	8:30		17:00	
			07MAR2011	YES	6:00	YES	16:30	
			08MAR2011	YES	6:30		16:40	selber genommen
			09MAR2011	YES	7:15	YES	16:50	
			10MAR2011	YES	7:00	YES	18:00	
			11MAR2011	YES	6:45	YES	17:30	
			12MAR2011	YES	7:30	YES	18:40	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	13MAR2011	YES	7:15			
			14MAR2011	YES	7:30	YES	17:20	
			15MAR2011	YES	7:25	YES	17:30	
			16MAR2011	YES	7:30	YES	17:45	
			17MAR2011	YES	7:20	YES	17:45	
			18MAR2011	YES	6:50	YES	18:10	
			19MAR2011	YES	8:20	YES	17:15	
			20MAR2011	YES	8:15	YES	17:15	
			21MAR2011	YES	7:15	YES	17:30	selbst genommen am Abend am Abend selbst genommen
			22MAR2011	YES	7:20	YES	16:30	
			23MAR2011	YES	7:15	YES	16:50	
			24MAR2011	YES	7:00	YES	16:50	
			25MAR2011	YES	7:30	YES	17:55	
			26MAR2011	YES	8:30	YES	17:55	
			27MAR2011	YES	8:50	YES	18:00	
			28MAR2011	YES	7:45	YES	17:30	
			29MAR2011	YES	5:50	YES	17:45	
			30MAR2011	YES	6:30	YES	17:35	
			31MAR2011	YES	7:30	YES	18:00	
			01APR2011	YES	7:15	YES	17:20	
			02APR2011	YES	7:10	YES	18:00	
			03APR2011	YES	7:30	YES	18:30	
			04APR2011	YES	6:50	YES	17:30	
			05APR2011	YES	7:20	YES	17:20	
			06APR2011	YES	7:15	YES	17:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	07APR2011	YES	7:00	YES	18:00	
			08APR2011	YES	7:20	YES	18:30	
			09APR2011	YES	8:25			
			10APR2011	YES	8:05	YES	17:20	
			11APR2011	YES	7:10	YES	17:10	
			12APR2011	YES	8:30			
			13APR2011	YES	7:20	YES	17:30	
			14APR2011	YES	7:30	YES	17:35	
			15APR2011	YES	6:30	YES	17:10	
			16APR2011	YES	8:20	YES	17:00	
			17APR2011	YES	8:30	YES	16:50	
			18APR2011	YES	7:00	YES	17:50	
			19APR2011	YES	6:45	YES	18:00	
			20APR2011	YES	7:20	YES	17:00	
			21APR2011	YES	7:20	YES	17:30	
			22APR2011	YES	6:30	YES	17:15	
			23APR2011	YES	8:30	YES	18:00	
			24APR2011	YES	7:45	YES	20:00	
			25APR2011	YES	8:50	YES	16:20	
			26APR2011	YES	6:45	YES	17:00	
			27APR2011	YES	6:30	YES	17:55	
			28APR2011	YES	7:20	YES	17:30	
			29APR2011	YES	7:30	YES	17:30	
			30APR2011	YES	8:30	YES	17:40	
			01MAY2011	YES	8:35	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	02MAY2011	YES	7:30	YES	17:50	
			03MAY2011	YES	7:15			selber genommen
			04MAY2011	YES				
			05MAY2011	YES	7:15	YES	17:30	
			06MAY2011	YES	8:20	YES	21:00	nach dem Essen wegen Geb.Tagsfeier
			07MAY2011	YES	9:45	YES	16:50	
			08MAY2011	YES	8:30	YES	19:00	
			09MAY2011	YES	7:30	YES	17:30	
			10MAY2011	YES	7:20	YES	17:30	
			11MAY2011	YES	7:30	YES	16:50	
			12MAY2011	YES	7:30	YES	17:30	
			13MAY2011	YES	6:00	YES	17:20	
			14MAY2011	YES	7:30	YES	19:15	
			15MAY2011	YES	7:20	YES	17:30	
			16MAY2011	YES	7:20	YES	18:30	
			17MAY2011	YES	6:30		17:00	
			18MAY2011	YES	6:45	YES	16:30	
			19MAY2011	YES	7:20	YES	17:30	
			20MAY2011	YES	7:10	YES	17:00	
			21MAY2011	YES	7:20	YES	16:50	
			22MAY2011	YES	6:50	YES	17:25	
			23MAY2011	YES	7:30	YES	17:30	
			24MAY2011	YES	6:05	YES	16:55	
			25MAY2011	YES	7:30	YES	17:50	
			26MAY2011	YES	6:45	YES	17:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	27MAY2011	YES	7:15	YES	17:45	
			28MAY2011	YES	7:30	YES	19:40	
			29MAY2011	YES	5:40	YES	17:50	
			30MAY2011	YES	7:15	YES	17:00	
			31MAY2011	YES	7:05	YES	17:20	
			01JUN2011	YES	7:20	YES	16:35	
			02JUN2011	YES	7:20	YES	17:30	
			03JUN2011	YES	7:05	YES	17:30	
			04JUN2011	YES	8:35	YES	20:00	Nach Abendessen, da wir eingeladen waren
			05JUN2011	YES	8:50	YES	19:05	
			06JUN2011	YES	7:20	YES	17:30	
			07JUN2011	YES	5:20	YES	17:15	selber genommen (Tabletten)
			08JUN2011	YES	7:10	YES	17:00	
			09JUN2011	YES	7:15	YES	17:30	
			10JUN2011	YES	8:00	YES	19:30	
			11JUN2011	YES	8:05		17:30	
			12JUN2011	YES	8:45	YES	17:00	
			13JUN2011	YES	8:00	YES	17:30	
			14JUN2011	YES	7:00	YES	17:30	
			15JUN2011	YES	7:20	YES	17:45	
			16JUN2011	YES	7:30	YES	18:00	
			17JUN2011	YES	7:40	YES	18:20	
			18JUN2011	YES	7:45	YES	17:20	
			19JUN2011	YES	8:20	YES	18:00	
			20JUN2011		7:30	YES	17:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	21JUN2011	YES	7:05	YES	17:35	
			22JUN2011	YES	7:00	YES	16:30	
			23JUN2011	YES	9:05	YES	16:45	1 Tablette noch Frühstück (vergessen)
			24JUN2011	YES	6:50	YES	17:00	
			25JUN2011	YES	6:00	YES	17:45	
			26JUN2011	YES	7:30	YES	17:30	
			27JUN2011	YES	6:30	YES	16:45	
			28JUN2011	YES	7:20	YES	16:45	
			29JUN2011	YES	7:15	YES	18:00	
			30JUN2011	YES	6:50	YES	17:10	
			01JUL2011	YES	5:55	YES	17:20	
			02JUL2011	YES	6:00	YES	17:30	
			03JUL2011	YES	6:30	YES	16:25	
			04JUL2011	YES	6:05	YES	16:30	
			05JUL2011	YES	5:45			
			06JUL2011	YES	7:00	YES	17:15	Meine Mama nimmt die Tabletten immer wieder von selbst!
			07JUL2011	YES	7:15	YES	17:50	
			08JUL2011	YES	7:00	YES	17:30	
			09JUL2011	YES	7:30	YES	18:30	
			10JUL2011	YES	7:30	YES	17:20	
			11JUL2011	YES	7:15	YES	16:50	
			12JUL2011	YES	6:55	YES	17:00	
			13JUL2011	YES	7:05	YES	17:30	
			14JUL2011	YES	7:20	YES	17:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	15JUL2011	YES	9:00	YES	17:50	
			16JUL2011	YES	8:45	YES	19:25	
			17JUL2011	YES	8:50	YES	18:30	
			18JUL2011	YES	7:20	YES	17:00	
			19JUL2011	YES	6:45	YES	16:40	
			20JUL2011	YES	7:20	YES	17:10	
			21JUL2011	YES	7:20	YES	20:30	Nach Einladung! Tabletten vergessen.
			22JUL2011	YES	7:15	YES	18:10	
			23JUL2011	YES	7:05	YES	17:30	
			24JUL2011	YES	7:20	YES	16:50	
			25JUL2011	YES	7:15	YES	17:45	
			26JUL2011	YES	7:30	YES	17:35	
			27JUL2011	YES	6:20	YES	16:20	Tabletten selber eingenommen
			28JUL2011	YES	7:30	YES	17:30	
			29JUL2011	YES	7:20	YES	17:45	
			30JUL2011	YES	7:10	YES	18:00	
			31JUL2011	YES	8:30	YES	16:50	
			01AUG2011	YES	8:00	YES	17:45	
			02AUG2011	YES	6:00	YES	17:20	
			04AUG2011	YES	6:20	YES	17:30	
			05AUG2011	YES	7:15	YES	17:20	
			06AUG2011	YES	7:30	YES	19:30	
			07AUG2011	YES	7:15	YES	18:00	
			08AUG2011	YES	7:15	YES	17:15	
			09AUG2011	YES	7:15	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	10AUG2011		7:15	YES	17:30	
			11AUG2011	YES	7:05	YES	17:35	
			12AUG2011	YES	6:45	YES	17:25	
			13AUG2011	YES	7:15	YES	16:50	
			14AUG2011	YES	8:20	YES	20:05	
			15AUG2011	YES	6:00	YES	17:30	
			16AUG2011	YES	7:15	YES	17:35	
			17AUG2011	YES	6:45	YES	17:30	
			18AUG2011		6:50	YES	17:30	
			19AUG2011	YES	7:05	YES	20:00	
			20AUG2011	YES	9:00	YES	19:30	
			21AUG2011	YES	7:45	YES	17:45	
			22AUG2011	YES	7:50	YES	19:30	
			23AUG2011	YES	8:50	YES	17:00	
			24AUG2011	YES	8:30	YES	17:15	
			25AUG2011	YES	5:30	YES	18:05	
			26AUG2011	YES	7:00	YES	18:00	
			27AUG2011	YES	7:20	YES	17:30	
			28AUG2011	YES	6:50			
			29AUG2011	YES	6:30	YES	17:45	
			30AUG2011	YES	7:30	YES	18:05	
			31AUG2011	YES	7:30	YES	18:00	ab 31.08.2011 Euthyrox 75 mg
			01SEP2011	YES	6:15	YES	17:05	
			02SEP2011	YES	6:00		17:20	
			03SEP2011	YES	8:45	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	04SEP2011	YES	8:30	YES	17:10	
			05SEP2011	YES	6:30	YES	17:10	
			06SEP2011	YES	7:30	YES	18:10	
			07SEP2011	YES	7:30	YES	18:00	
			08SEP2011	YES	6:50	YES	18:05	
			09SEP2011	YES	6:00	YES	18:00	
			10SEP2011	YES	8:50	YES	17:20	
			11SEP2011	YES	8:45	YES	17:50	
			12SEP2011	YES	7:35	YES	18:05	
			13SEP2011	YES	7:00	YES	17:25	
			14SEP2011	YES	7:05	YES	17:20	
			15SEP2011	YES	7:00	YES	17:45	
			16SEP2011	YES	6:50	YES	17:50	
			17SEP2011	YES	8:35	YES	18:00	
			18SEP2011	YES	7:20	YES	17:45	
			19SEP2011	YES	7:10	YES	18:05	
			20SEP2011	YES	7:10	YES	17:05	
			21SEP2011	YES	7:35	YES	18:08	
			22SEP2011	YES	6:00	YES	17:40	
			23SEP2011	YES	6:45	YES	17:30	
			24SEP2011	YES	8:45	YES	17:45	
			25SEP2011	YES				
			26SEP2011	YES	6:15	YES	17:20	
			27SEP2011	YES	6:00	YES	18:05	
			28SEP2011	YES	5:55	YES	17:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	29SEP2011	YES	6:00	YES	17:35	Schilddrüsenambulanz
			30SEP2011	YES	6:00	YES	18:00	
			01OCT2011	YES	8:20	YES	18:05	
			02OCT2011	YES	7:30	YES	17:30	
			03OCT2011	YES	6:15	YES	17:45	
			04OCT2011	YES	6:05	YES	17:30	
			05OCT2011	YES	7:15	YES	16:35	
			06OCT2011	YES	7:05	YES	18:20	
			07OCT2011	YES	8:35	YES	17:10	
			08OCT2011	YES	7:45	YES	17:50	
			09OCT2011	YES	8:10	YES	18:05	
			10OCT2011	YES	8:30	YES	17:00	
			11OCT2011	YES	6:50	YES	17:50	
			12OCT2011	YES	8:25	YES	17:20	
			13OCT2011		6:30	YES	18:00	
			14OCT2011	YES	6:45	YES	16:30	
			15OCT2011	YES	8:35	YES	17:35	
			16OCT2011	YES	8:20	YES	18:00	
			17OCT2011	YES	6:35	YES	16:45	
			18OCT2011	YES	6:50	YES	17:50	
			19OCT2011	YES	5:50		16:50	
			20OCT2011	YES	6:50	YES	17:58	
			21OCT2011	YES	8:30	YES	18:30	
			22OCT2011	YES	8:45	YES	18:30	
			23OCT2011	YES	8:05	YES	18:20	

1=TU München, 2=UK Ulm, 4=LMU München, 5=Charite Berlin, 8=UK Aachen, 9=Magdeburg, 11=UK Tübingen, 12=Elmshorn, 13=Bochum
16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	051	21	24OCT2011	YES	5:40	YES	17:10	
			25OCT2011	YES				
	056	5	05NOV2000	YES	6:15	YES	17:50	
			21APR2010			YES	18:30	
			22APR2010	YES	6:10	YES	18:30	
			23APR2010	YES	6:10	YES	18:30	
			24APR2010	YES	6:10	YES	18:50	
			25APR2010	YES	6:10	YES	18:30	
			26APR2010	YES	6:10	YES	19:15	
			27APR2010	YES	6:10	YES	18:00	
			28APR2010	YES	6:10	YES	18:40	
			29APR2010	YES	6:10	YES	19:45	
			30APR2010		6:10	YES	18:45	
			01MAY2010	YES	6:10	YES	20:00	
			02MAY2010	YES	6:10	YES	21:30	
			03MAY2010	YES	6:10	YES	19:00	
			04MAY2010	YES	6:10	YES	19:30	
			05MAY2010	YES	6:10	YES	19:30	
			06MAY2010	YES	6:10	YES	18:00	
			07MAY2010	YES	6:10	YES	21:00	
			08MAY2010	YES	6:10	YES	18:10	
			09MAY2010	YES	6:12	YES	19:20	
			10MAY2010	YES	6:10	YES	17:35	
			11MAY2010	YES	6:10	YES	18:55	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	12MAY2010	YES	6:10	YES	19:15	
			13MAY2010	YES	6:15	YES	18:45	
			14MAY2010	YES	6:15	YES	18:25	
			15MAY2010	YES	6:15	YES	18:00	
			16MAY2010	YES	6:15	YES	20:10	
			17MAY2010	YES	6:15	YES	18:00	
			18MAY2010	YES	6:15	YES	20:15	
			19MAY2010			YES	18:40	
			20MAY2010	YES	6:20	YES	18:00	
			21MAY2010	YES	6:20	YES	18:30	
			22MAY2010	YES	6:15	YES	19:30	
			23MAY2010	YES	6:20	YES	18:00	
			24MAY2010	YES	6:15	YES	20:10	
			25MAY2010	YES	6:15	YES	18:00	
			26MAY2010	YES	6:15	YES	19:00	
			27MAY2010	YES	6:15	YES	17:45	
			28MAY2010	YES	6:15	YES	17:30	
			29MAY2010	YES	6:15	YES	18:20	
			30MAY2010	YES	6:15	YES	18:30	
			31MAY2010	YES	6:15	YES	18:45	
			01JUN2010	YES	6:15	YES	17:10	
			02JUN2010	YES	6:15	YES	17:20	
			03JUN2010	YES	6:15	YES	17:00	
			04JUN2010	YES	6:15	YES	17:00	
			05JUN2010	YES	6:15	YES	17:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	06JUN2010	YES	6:15	YES	17:45	
			07JUN2010	YES	6:15	YES	18:00	
			08JUN2010	YES	6:15	YES	17:30	
			09JUN2010	YES	6:15	YES	17:40	
			10JUN2010	YES	6:15	YES	17:30	Ich glaube - diese habe ich vergessen!
			11JUN2010	YES	6:10	YES	17:00	
			12JUN2010	YES	6:15	YES	17:30	
			13JUN2010	YES	6:15	YES	18:00	
			14JUN2010	YES	6:00	YES	17:30	
			15JUN2010	YES	6:10	YES	18:30	
			16JUN2010	YES	6:10	YES	18:30	
			17JUN2010	YES	6:10	YES	18:30	
			18JUN2010	YES	6:10	YES	18:30	
			19JUN2010	YES	6:15	YES	18:50	
			20JUN2010	YES	6:15	YES	19:00	
			21JUN2010	YES	6:00	YES	18:45	
			22JUN2010	YES	6:10	YES	18:15	
			23JUN2010	YES	6:15	YES	18:15	
			24JUN2010	YES	6:15	YES	18:30	
			25JUN2010	YES	6:15	YES	19:00	
			26JUN2010	YES	6:15	YES	18:10	
			27JUN2010	YES	6:15	YES	18:45	
			28JUN2010	YES	6:15	YES	18:15	
			29JUN2010	YES	6:15	YES	17:15	
			30JUN2010	YES	6:00	YES	19:10	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	01JUL2010	YES	5:40		17:44	
			02JUL2010	YES	6:15	YES	17:50	
			03JUL2010	YES	6:45	YES	18:30	
			04JUL2010	YES	6:00	YES	19:00	
			05JUL2010	YES	8:30	YES	19:00	
			06JUL2010	YES	6:15	YES	18:45	
			07JUL2010	YES	6:20	YES	18:30	
			08JUL2010	YES	6:20	YES	20:45	
			09JUL2010	YES	6:15	YES	17:50	
			10JUL2010	YES	6:15	YES	18:00	
			11JUL2010	YES	6:15	YES	19:15	
			12JUL2010	YES	6:30	YES	17:30	
			13JUL2010	YES	6:00			
			13JUL2010			YES	20:40	
			14JUL2010	YES	6:15	YES	19:00	
			15JUL2010	YES	6:15	YES	19:30	
			16JUL2010	YES	6:15	YES	17:10	
			17JUL2010	YES	6:15	YES	18:55	
			18JUL2010	YES	6:15	YES	18:15	
			19JUL2010	YES	6:15	YES	17:45	
			20JUL2010	YES	6:15	YES	18:30	
			21JUL2010	YES	6:15	YES	18:30	
			22JUL2010	YES	6:10	YES	18:00	
			23JUL2010	YES	6:15	YES	18:30	
			24JUL2010	YES	6:15	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	25JUL2010	YES	6:15	YES	18:30	
			26JUL2010	YES	6:10	YES	17:30	
			27JUL2010	YES	6:15	YES	18:30	
			28JUL2010	YES	6:10	YES	18:00	
			29JUL2010	YES	6:15	YES	17:45	
			30JUL2010	YES	6:10	YES	18:00	
			31JUL2010	YES	6:15	YES	17:30	
			01AUG2010	YES	6:15	YES	18:00	
			02AUG2010	YES	6:15	YES	18:20	
			03AUG2010	YES	6:10	YES	17:30	
			04AUG2010	YES	6:15	YES	17:30	
			05AUG2010	YES	6:10	YES	18:00	
			06AUG2010	YES	6:10	YES	17:30	
			07AUG2010	YES	6:15	YES	18:30	
			08AUG2010	YES	6:10	YES	18:15	
			09AUG2010	YES	6:10	YES	18:15	
			10AUG2010	YES	6:20	YES	19:30	
			11AUG2010	YES	6:10	YES	18:10	
			12AUG2010	YES	5:45	YES	17:15	
			13AUG2010	YES	6:15	YES	17:50	
			14AUG2010	YES	6:10	YES	18:00	
			15AUG2010	YES	6:10	YES	19:30	
			16AUG2010	YES	6:00	YES	17:30	
			17AUG2010	YES	6:15	YES	18:50	
			18AUG2010	YES	6:30	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	19AUG2010	YES	6:00	YES	17:45	
			20AUG2010	YES	6:15	YES	17:45	
			21AUG2010	YES	6:15	YES	18:30	
			22AUG2010	YES	6:15	YES	18:00	
			23AUG2010	YES	6:20	YES	17:45	
			24AUG2010	YES	6:15	YES	18:00	
			25AUG2010	YES	6:15	YES	17:30	
			26AUG2010	YES	6:30	YES	17:00	
			27AUG2010	YES	6:15	YES	17:45	
			28AUG2010	YES	6:15	YES	18:15	
			29AUG2010	YES	6:15	YES	18:45	
			30AUG2010	YES	6:15	YES	17:30	
			31AUG2010	YES	6:10	YES	17:30	
			01SEP2010	YES	6:15	YES	17:30	
			02SEP2010	YES	6:10	YES	17:45	
			03SEP2010	YES	6:15	YES	17:00	
			04SEP2010	YES	6:10	YES	17:30	
			05SEP2010	YES	6:00	YES	19:00	
			06SEP2010	YES	6:10	YES	18:00	
			07SEP2010	YES	6:10	YES	17:30	
			08SEP2010	YES	6:10		18:30	x vergessen
			09SEP2010	YES	6:15	YES	17:30	
			10SEP2010	YES	6:15	YES	17:45	
			11SEP2010	YES	6:15	YES	18:00	
			12SEP2010	YES	6:15	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	13SEP2010	YES	6:15	YES	19:30	
			14SEP2010	YES	6:15	YES	18:40	
			15SEP2010	YES	6:15	YES	18:15	
			16SEP2010	YES	6:00	YES	17:45	
			17SEP2010	YES	6:10	YES	18:30	
			18SEP2010	YES	6:15	YES	18:45	
			19SEP2010	YES	6:15	YES	18:00	
			20SEP2010	YES	6:15	YES	17:45	
			21SEP2010	YES	6:15	YES	18:00	
			22SEP2010	YES	6:10	YES	17:50	
			23SEP2010	YES	6:15	YES	17:45	
			24SEP2010	YES	6:15	YES	18:00	
			25SEP2010	YES	6:15	YES	18:20	
			26SEP2010	YES	6:15	YES	18:50	
			27SEP2010	YES	6:20	YES	17:30	
			28SEP2010	YES	6:15		18:50	
			29SEP2010	YES	6:15	YES	17:30	
			30SEP2010	YES	6:10	YES	17:00	
			01OCT2010	YES	6:10	YES	17:00	
			02OCT2010	YES	6:15		18:30	
			03OCT2010	YES	6:10	YES	19:00	
			04OCT2010	YES	6:15	YES	18:30	
			05OCT2010	YES	6:15			
			05OCT2010			YES	18:00	
			06OCT2010	YES	6:15	YES	17:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	07OCT2010	YES	6:10	YES	18:00	
			08OCT2010	YES	6:10	YES	17:45	
			09OCT2010	YES	6:10	YES	18:15	
			10OCT2010	YES	6:10	YES	17:50	
			11OCT2010	YES	6:10	YES	17:00	
			12OCT2010	YES	6:10	YES	17:30	
			13OCT2010	YES	6:10	YES	19:20	
			14OCT2010	YES	5:30	YES	16:30	
			15OCT2010	YES	6:10	YES	17:40	
			16OCT2010	YES	6:10	YES	17:45	
			17OCT2010	YES	6:10	YES	17:45	
			18OCT2010	YES	6:10	YES	18:30	
			19OCT2010	YES	6:10	YES	17:40	
			20OCT2010	YES	6:10	YES	18:10	
			21OCT2010	YES	5:30	YES	17:30	
			22OCT2010	YES	6:10	YES	17:45	
			23OCT2010	YES	6:15	YES	17:45	
			24OCT2010	YES	6:15		17:45	
			25OCT2010	YES	6:30	YES	17:45	
			26OCT2010	YES	6:15	YES	18:00	
			27OCT2010	YES	6:15	YES	18:00	
			28OCT2010	YES	5:30	YES	17:00	
			29OCT2010	YES	6:15	YES	17:30	
			30OCT2010	YES	6:15	YES	17:15	
			31OCT2010	YES	6:15	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	01NOV2010	YES	6:15	YES	17:50	
			02NOV2010	YES	6:15	YES	17:45	
			03NOV2010	YES	6:15	YES	16:45	
			04NOV2010	YES	5:30	YES	17:45	
			06NOV2010	YES	6:15		17:45	
			07NOV2010	YES	6:15	YES	17:50	
			08NOV2010	YES	6:15	YES	17:30	
			09NOV2010	YES	6:15	YES	17:20	
			10NOV2010	YES	4:50	YES	19:30	
			11NOV2010	YES	7:00	YES	20:00	
			12NOV2010	YES	6:15	YES	17:00	
			13NOV2010	YES	6:30	YES	18:00	
			14NOV2010	YES	6:15	YES	17:00	
			15NOV2010	YES	6:15	YES	17:30	
			16NOV2010	YES	6:15	YES	17:00	
			17NOV2010	YES	6:15	YES	17:20	
			18NOV2010	YES	5:45	YES	18:00	
			19NOV2010	YES	6:05	YES	17:30	
			20NOV2010	YES	7:20	YES	17:30	
			21NOV2010	YES	6:05	YES	18:00	
			22NOV2010	YES	6:15	YES	18:00	
			23NOV2010	YES	6:15	YES	18:30	
			24NOV2010	YES	6:15	YES	17:15	
			25NOV2010	YES	5:30	YES	17:00	
			26NOV2010	YES	6:20	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	27NOV2010	YES	7:00	YES	18:00	
			28NOV2010	YES	6:28	YES	17:45	
			29NOV2010	YES	6:15	YES	17:30	
			30NOV2010	YES	6:15	YES	17:00	
			01DEC2010	YES	6:15	YES	17:30	
			02DEC2010	YES	5:30	YES	17:30	
			03DEC2010	YES	6:15	YES	17:30	
			04DEC2010	YES	6:15	YES	18:30	
			05DEC2010	YES	6:15	YES	17:30	
			06DEC2010	YES	6:15	YES	18:00	
			07DEC2010	YES	6:15	YES	18:30	
			08DEC2010	YES	6:15	YES	18:20	
			09DEC2010	YES	5:30	YES	17:35	
			10DEC2010	YES	6:15	YES	17:30	
			11DEC2010	YES	6:15	YES	17:00	
			12DEC2010	YES	7:15	YES	17:50	
			13DEC2010	YES	6:15	YES	17:00	
			14DEC2010	YES	6:15	YES	17:30	
			15DEC2010	YES	6:15		17:50	
			16DEC2010	YES	5:30	YES	18:00	
			17DEC2010	YES	6:30	YES	17:30	
			18DEC2010	YES	7:00	YES	18:00	
			19DEC2010	YES	6:30	YES	17:45	
			20DEC2010	YES	6:30	YES	17:45	
			21DEC2010	YES	6:15	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	22DEC2010	YES	6:15	YES	17:00	
			23DEC2010	YES	5:45	YES	17:00	
			24DEC2010	YES	6:15	YES	23:00	
			25DEC2010	YES	6:15	YES	18:00	
			26DEC2010	YES	7:30	YES	17:30	
			27DEC2010	YES	6:15	YES	17:00	
			28DEC2010	YES	6:15	YES	17:30	
			29DEC2010	YES	6:15	YES	18:00	
			30DEC2010	YES	5:45	YES	17:50	
			31DEC2010	YES	6:15	YES	17:30	
			01JAN2011	YES	6:30	YES	18:00	
			02JAN2011	YES	6:15	YES	18:30	
			03JAN2011	YES	6:15	YES	18:20	
			04JAN2011	YES	6:15			
			05JAN2011	YES	6:15	YES	18:00	
			06JAN2011	YES	6:15	YES	17:45	
			07JAN2011	YES	6:15	YES	18:15	
			08JAN2011	YES	6:15	YES	17:30	
			09JAN2011	YES	6:30	YES	18:00	
			10JAN2011	YES	6:15	YES	17:30	
			11JAN2011	YES	6:15	YES	18:30	
			12JAN2011	YES	6:15	YES	18:00	
			13JAN2011	YES	6:15	YES	18:00	
			14JAN2011	YES	6:15	YES	17:00	
			15JAN2011	YES	6:15	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	16JAN2011	YES	6:15	YES	20:00	
			17JAN2011	YES	6:15	YES	17:20	
			18JAN2011	YES	6:15	YES	19:50	
			19JAN2011	YES	6:15	YES	18:00	
			20JAN2011	YES	6:15	YES	18:00	
			21JAN2011	YES	6:15	YES	17:00	
			22JAN2011	YES	6:25	YES	18:00	
			23JAN2011	YES	6:15	YES	17:45	
			24JAN2011	YES	6:15	YES	17:50	
			25JAN2011	YES	6:15	YES	20:00	
			26JAN2011	YES	6:15	YES	17:00	
			27JAN2011	YES	6:15	YES	17:30	
			28JAN2011	YES	6:15	YES	18:00	
			29JAN2011	YES	6:15	YES	17:50	
			30JAN2011	YES	7:45	YES	17:50	
			31JAN2011	YES	6:15	YES	17:50	
			01FEB2011	YES	6:15	YES	18:00	
			02FEB2011	YES	6:15	YES	18:25	
			03FEB2011	YES	6:15	YES	17:30	
			04FEB2011	YES	6:15	YES	17:50	
			05FEB2011	YES	7:15	YES	17:50	
			06FEB2011	YES	6:15	YES	17:50	
			07FEB2011	YES	6:15	YES	18:00	
			08FEB2011	YES	6:15	YES	17:40	
			09FEB2011	YES	6:15	YES	17:50	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	10FEB2011	YES	6:15	YES	18:00	
			11FEB2011	YES	6:15	YES	17:40	
			12FEB2011	YES	6:15	YES	17:40	
			13FEB2011	YES	6:15	YES	19:15	
			14FEB2011	YES	6:15	YES	17:15	
			15FEB2011	YES	6:15	YES	17:00	
			16FEB2011	YES	6:15	YES	18:45	
			17FEB2011	YES	6:15	YES	17:45	
			18FEB2011	YES	6:15	YES	17:40	
			19FEB2011	YES	6:15	YES	17:40	
			20FEB2011	YES	7:30	YES	17:45	
			21FEB2011	YES	6:15	YES	18:00	
			22FEB2011	YES	6:15	YES	17:35	
			23FEB2011	YES	6:15	YES	17:30	
			24FEB2011	YES	6:15		17:30	
			25FEB2011	YES	6:15		17:50	
			26FEB2011	YES	7:20	YES	18:00	
			27FEB2011	YES	6:15	YES	17:30	
			28FEB2011	YES	6:15	YES	18:00	
			01MAR2011	YES	6:15	YES	18:00	
			02MAR2011	YES	6:15	YES	17:30	
			03MAR2011	YES	6:15	YES	18:50	
			04MAR2011	YES	6:15	YES	18:00	
			05MAR2011	YES	7:30	YES	17:50	
			06MAR2011	YES	6:15	YES	18:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	07MAR2011	YES	6:15	YES	18:10	
			08MAR2011	YES	6:15	YES	17:50	
			09MAR2011	YES	6:15	YES	17:55	
			10MAR2011	YES	6:15	YES	18:00	
			11MAR2011	YES	6:15	YES	17:55	
			12MAR2011	YES	7:35	YES	18:00	
			13MAR2011	YES	6:15	YES	18:00	
			14MAR2011	YES	6:15		17:40	
			15MAR2011	YES	6:15	YES	18:00	
			16MAR2011	YES	6:15	YES	17:45	
			17MAR2011	YES	6:15	YES	17:30	
			18MAR2011	YES	6:15	YES	17:30	
			19MAR2011	YES	7:30		18:20	
			20MAR2011	YES	6:15	YES	17:30	
			21MAR2011	YES	6:15	YES	18:50	
			22MAR2011	YES	6:15	YES	18:00	
			23MAR2011	YES	6:15	YES	18:00	
			24MAR2011	YES	6:15	YES	18:00	
			25MAR2011	YES	6:15	YES	18:00	
			26MAR2011	YES	7:30	YES	18:40	
			27MAR2011	YES	6:30	YES	19:00	
			28MAR2011	YES	6:15	YES	18:45	
			29MAR2011	YES	6:15	YES	18:00	
			30MAR2011	YES	6:15	YES	18:00	
			31MAR2011	YES	6:15	YES	17:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	056	5	01APR2011	YES	6:15	YES	18:00	
			02APR2011	YES	7:30	YES	18:50	
			03APR2011	YES	6:15	YES	18:10	
			04APR2011	YES	6:15	YES	17:30	
			05APR2011	YES	6:15	YES	17:00	
			06APR2011	YES	6:15		17:50	
			07APR2011	YES	6:15	YES	18:30	
			08APR2011	YES	6:15	YES	17:50	
			09APR2011	YES	7:30	YES	17:45	
			10APR2011	YES	6:15	YES	17:50	
			11APR2011	YES	6:15	YES	18:10	
			12APR2011	YES	6:15	YES	18:30	
			13APR2011	YES	6:15	YES	18:50	
			14APR2011	YES	6:15	YES	18:50	
			15APR2011	YES	6:15	YES	17:50	
			16APR2011	YES	6:15	YES	18:00	
			17APR2011	YES	6:15	YES	18:45	
			18APR2011	YES	6:15	YES	18:00	
			19APR2011	YES	6:00			
	058	1	28DEC2010	YES	8:30	YES	18:30	
			29DEC2010	YES	8:30	YES	18:15	
			30DEC2010	YES	8:30	YES	18:15	
			31DEC2010	YES	8:40	YES	18:30	
			01JAN2011	YES	8:30	YES	18:40	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	02JAN2011	YES	9:00	YES	18:00	
			03JAN2011	YES	8:35	YES	18:30	
			04JAN2011	YES	8:30	YES	18:40	
			05JAN2011	YES	8:30	YES	18:30	
			06JAN2011	YES	8:30	YES	18:30	
			07JAN2011	YES	8:35	YES	18:35	
			08JAN2011	YES	8:30	YES	18:30	
			09JAN2011	YES	8:30	YES	18:30	
			10JAN2011	YES	8:40	YES	18:40	
			11JAN2011	YES	8:35	YES	18:30	
			12JAN2011	YES	8:30	YES	18:30	
			13JAN2011	YES	8:30	YES	18:35	
			14JAN2011	YES	8:30	YES	18:30	
			15JAN2011	YES	8:30	YES	18:30	
			16JAN2011	YES	8:35	YES	18:30	
			17JAN2011	YES	8:30	YES	18:30	
			18JAN2011	YES	8:40	YES	18:30	
			19JAN2011	YES	8:30	YES	18:35	
			20JAN2011	YES	8:30	YES	18:30	
			21JAN2011	YES	8:30			
			22JAN2011	YES	8:30	YES	18:30	
			23JAN2011	YES	8:30	YES	18:30	
			24JAN2011	YES	8:30	YES	18:30	
			25JAN2011	YES	7:30	YES	18:30	
			26JAN2011	YES	7:35	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	27JAN2011	YES	7:30	YES	18:30	
			28JAN2011	YES	7:30	YES	18:30	
			29JAN2011	YES	7:30	YES	18:30	
			30JAN2011	YES	7:35	YES	18:45	
			31JAN2011	YES	7:30	YES	18:30	
			01FEB2011	YES	7:30	YES	18:30	
			02FEB2011	YES	7:30	YES	18:30	
			03FEB2011	YES	7:30	YES	18:30	
			04FEB2011	YES	7:30	YES	18:30	
			05FEB2011	YES	7:30	YES	18:30	
			06FEB2011	YES	7:30	YES	18:30	
			07FEB2011	YES	7:30	YES	18:30	
			08FEB2011	YES	7:30	YES	18:30	
			09FEB2011	YES	7:30	YES	18:30	
			10FEB2011	YES	7:30	YES	18:45	
			11FEB2011	YES	7:45	YES	18:30	
			12FEB2011	YES	8:30		18:45	
			13FEB2011	YES	8:30	YES	18:45	
			14FEB2011		7:30	YES	18:30	
			15FEB2011	YES	7:30	YES	18:30	
			16FEB2011	YES	7:30	YES	18:30	
			17FEB2011		7:30		18:45	
			18FEB2011	YES	7:30	YES	18:45	
			19FEB2011	YES	7:30	YES	18:30	
			20FEB2011	YES	7:30	YES	18:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	21FEB2011	YES	7:30	YES	18:30	
			22FEB2011	YES	7:30	YES	18:30	
			23FEB2011	YES	7:30	YES	18:45	
			24FEB2011	YES	7:30	YES	18:30	
			25FEB2011	YES	7:30	YES	18:45	
			26FEB2011	YES	7:30	YES	18:30	
			27FEB2011	YES	7:30	YES	18:30	
			28FEB2011	YES	7:30	YES	18:45	
			01MAR2011	YES	7:30	YES	18:45	
			02MAR2011	YES	7:30	YES	18:30	
			03MAR2011	YES	7:30	YES	18:30	
			04MAR2011	YES	7:30	YES	18:30	
			05MAR2011	YES	7:30	YES	18:30	
			06MAR2011	YES	7:30	YES	18:00	
			07MAR2011	YES	7:30	YES	18:30	
			08MAR2011	YES	7:30	YES	18:30	
			09MAR2011	YES	7:30	YES	18:30	
			10MAR2011	YES	7:30	YES	18:30	
			11MAR2011	YES	7:30	YES	18:30	
			12MAR2011	YES	7:30	YES	18:30	
			13MAR2011	YES	7:30	YES	17:30	
			14MAR2011	YES	7:30	YES	18:30	
			15MAR2011	YES	7:30		18:30	
			16MAR2011	YES	7:30	YES	18:30	
			17MAR2011	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	18MAR2011	YES	7:30	YES	18:30	
			19MAR2011	YES	7:30	YES	18:30	
			20MAR2011	YES	7:30	YES	18:30	
			21MAR2011	YES	7:30	YES	18:30	
			22MAR2011	YES	7:30	YES	18:30	
			23MAR2011	YES	7:30	YES	18:30	
			24MAR2011	YES	7:30	YES	19:00	
			25MAR2011	YES	7:30	YES	18:30	
			26MAR2011	YES	7:30	YES	17:30	
			27MAR2011	YES	7:30	YES	18:00	
			28MAR2011	YES	7:30	YES	18:45	
			29MAR2011	YES	7:30			
			30MAR2011	YES	7:30	YES	18:30	
			31MAR2011	YES	7:30	YES	18:30	
			01APR2011	YES	7:30	YES	18:30	
			02APR2011	YES	7:30	YES	18:30	
			03APR2011	YES	7:30	YES	18:00	
			04APR2011	YES	7:30	YES	18:30	
			05APR2011	YES	7:30	YES	18:30	
			06APR2011	YES	7:30	YES	18:30	
			07APR2011	YES	7:30	YES	18:30	
			08APR2011	YES	7:30	YES	18:30	
			09APR2011	YES	7:30	YES	18:30	
			10APR2011	YES	7:30	YES	18:00	
			11APR2011	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	12APR2011	YES	7:30	YES	18:40	
			13APR2011	YES	7:30	YES	18:30	
			14APR2011	YES	7:30	YES	18:30	
			15APR2011	YES	7:30	YES	18:30	
			16APR2011	YES	7:30	YES	18:30	
			17APR2011	YES	7:30	YES	18:00	
			18APR2011	YES	7:30	YES	18:30	
			19APR2011	YES	7:30	YES	18:30	
			20APR2011	YES	7:30	YES	18:30	
			21APR2011	YES	7:30	YES	18:30	
			22APR2011	YES	7:30	YES	18:30	
			23APR2011	YES	7:30	YES	18:30	
			24APR2011	YES	7:30	YES	18:30	
			25APR2011	YES	8:00	YES	18:30	
			26APR2011	YES	7:30	YES	18:30	
			27APR2011	YES	7:30	YES	18:30	
			28APR2011	YES	7:30	YES	18:30	
			29APR2011	YES	7:30	YES	18:30	
			30APR2011	YES	7:30	YES	18:30	
			01MAY2011	YES	7:30	YES	18:00	
			02MAY2011	YES	7:30	YES	18:45	
			03MAY2011	YES	7:30	YES	18:30	
			04MAY2011	YES	7:30	YES	18:30	
			05MAY2011	YES	7:30	YES	18:30	
			06MAY2011	YES	7:30		18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	07MAY2011	YES	7:30	YES	18:30	
			08MAY2011	YES	7:30	YES	18:00	
			09MAY2011	YES	7:30	YES	18:30	
			10MAY2011	YES	7:30	YES	18:30	
			11MAY2011	YES	7:30	YES	18:30	
			12MAY2011	YES	7:30	YES	18:30	
			13MAY2011	YES	7:30	YES	18:30	
			14MAY2011	YES	7:30	YES	18:30	
			15MAY2011	YES	7:30	YES	18:00	
			16MAY2011	YES	7:30	YES	18:30	
			17MAY2011	YES	7:30	YES	18:30	
			18MAY2011	YES	7:30	YES	18:30	
			19MAY2011	YES	7:30	YES	18:30	
			20MAY2011	YES	7:30	YES	18:30	
			21MAY2011	YES	7:30	YES	18:30	
			22MAY2011	YES	7:30	YES	18:15	
			23MAY2011	YES	7:30	YES	18:30	
			24MAY2011	YES	7:30	YES	18:30	
			25MAY2011	YES	7:30	YES	18:30	
			26MAY2011	YES	7:30	YES	18:30	
			27MAY2011	YES	7:30	YES	18:30	
			28MAY2011	YES	7:30	YES	18:45	
			29MAY2011	YES	7:30	YES	18:30	
			30MAY2011	YES	7:30	YES	18:45	
			31MAY2011	YES	7:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	01JUN2011	YES	7:30	YES	18:30	
			02JUN2011	YES	7:30	YES	18:30	
			03JUN2011	YES	7:30	YES	18:30	
			04JUN2011	YES	7:30	YES	18:30	
			05JUN2011	YES	7:30	YES	18:30	
			06JUN2011	YES	7:30	YES	18:30	
			07JUN2011	YES	7:30	YES	18:30	
			08JUN2011	YES	7:30	YES	18:00	
			09JUN2011	YES	7:30			
			10JUN2011			YES	18:30	
			11JUN2011	YES	8:30	YES	19:30	
			12JUN2011	YES	8:30	YES	19:30	
			13JUN2011	YES	8:30	YES	19:30	
			14JUN2011	YES	8:30	YES	19:30	
			15JUN2011	YES	8:30	YES	19:30	
			16JUN2011	YES	8:30	YES	19:30	
			17JUN2011	YES	8:30	YES	19:30	
			18JUN2011	YES	8:30	YES	19:30	
			19JUN2011	YES	8:30	YES	19:30	
			20JUN2011	YES	8:30	YES	19:30	
			21JUN2011	YES	8:30	YES	19:30	
			22JUN2011	YES	8:30	YES	19:30	
			23JUN2011	YES	8:30	YES	19:30	
			24JUN2011	YES	8:30	YES	19:30	
			25JUN2011	YES	8:30	YES	19:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	26JUN2011	YES	8:30	YES	19:30	
			27JUN2011	YES	7:30	YES	18:30	
			28JUN2011	YES	7:30	YES	18:30	
			29JUN2011	YES	7:30	YES	18:30	
			30JUN2011	YES	7:30	YES	18:30	
			01JUL2011	YES	7:30	YES	18:30	
			02JUL2011	YES	7:30	YES	18:30	
			03JUL2011	YES	7:30	YES	18:30	
			04JUL2011	YES	7:30	YES	18:30	
			05JUL2011	YES	7:30	YES	18:00	
			06JUL2011	YES	7:30	YES	18:30	
			07JUL2011	YES	7:30	YES	18:30	
			08JUL2011	YES	7:30	YES	19:00	
			09JUL2011	YES	8:00	YES	18:30	
			10JUL2011	YES	8:00	YES	18:00	
			11JUL2011	YES	7:30	YES	18:30	
			12JUL2011	YES	7:30	YES	18:30	
			13JUL2011	YES	7:30	YES	18:30	
			16JUL2011	YES	8:00	YES	18:00	
			17JUL2011	YES	8:00	YES	18:00	
			18JUL2011	YES	7:30	YES	18:30	
			19JUL2011	YES	7:30	YES	18:30	
			20JUL2011	YES	7:30	YES	18:30	
			21JUL2011	YES	7:30	YES	18:30	
			22JUL2011	YES	7:30	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	23JUL2011	YES	8:00	YES	18:00	
			24JUL2011		8:00	YES	18:00	
			25JUL2011	YES	7:30	YES	18:30	
			26JUL2011	YES	7:30	YES	18:30	
			27JUL2011	YES	7:30	YES	18:00	
			28JUL2011	YES	7:30	YES	18:30	
			29JUL2011	YES	7:30	YES	18:30	
			30JUL2011	YES	7:30	YES	18:30	
			31JUL2011	YES	8:00	YES	18:00	
			01AUG2011	YES	7:30	YES	18:30	
			02AUG2011	YES	7:30	YES	18:30	
			03AUG2011	YES	7:30	YES	18:30	
			04AUG2011	YES	7:30	YES	18:30	
			05AUG2011	YES	7:30	YES	18:30	
			06AUG2011	YES	7:30	YES	18:30	
			07AUG2011	YES	8:00	YES	18:00	
			08AUG2011	YES	7:30	YES	18:30	
			09AUG2011	YES	7:30	YES	18:30	
			10AUG2011	YES	7:30	YES	18:30	
			11AUG2011	YES	7:30	YES	18:30	
			12AUG2011	YES	7:30	YES	18:30	
			13AUG2011	YES	8:00	YES	18:30	
			14AUG2011	YES	8:00	YES	18:00	
			15AUG2011	YES	7:30	YES	18:30	
			16AUG2011	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	17AUG2011	YES	7:30	YES	18:30	
			18AUG2011	YES	7:30	YES	18:30	
			19AUG2011	YES	7:30	YES	18:30	
			20AUG2011	YES	7:30	YES	18:30	
			21AUG2011	YES	8:30	YES	18:00	
			22AUG2011	YES	8:30	YES	18:30	
			23AUG2011	YES	8:30	YES	18:30	
			24AUG2011	YES	7:30	YES	18:30	
			25AUG2011	YES	7:30	YES	18:30	
			26AUG2011	YES	7:30	YES	18:30	
			27AUG2011	YES	7:30	YES	19:00	
			28AUG2011	YES	8:00	YES	18:30	
			29AUG2011	YES	7:30	YES	18:30	
			30AUG2011	YES	7:30	YES	18:30	
			31AUG2011	YES	7:30	YES	18:30	
			01SEP2011	YES	7:30	YES	18:30	
			02SEP2011	YES	7:30	YES	18:30	
			03SEP2011	YES	7:30	YES	18:30	
			04SEP2011	YES	7:30	YES	18:00	
			05SEP2011	YES	7:30	YES	18:30	
			06SEP2011	YES	7:30	YES	18:30	
			07SEP2011	YES	7:30	YES	18:30	
			08SEP2011	YES	7:30	YES	18:30	
			09SEP2011	YES	7:30		18:30	
			10SEP2011	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	11SEP2011	YES	7:30	YES	18:30	
			12SEP2011	YES	7:30			
			12SEP2011	YES	7:30	YES	19:00	
			13SEP2011	YES	7:30	YES	18:30	
			14SEP2011	YES	7:30	YES	18:30	
			15SEP2011	YES	7:30	YES	18:30	
			16SEP2011	YES	7:30	YES	18:30	
			17SEP2011	YES	7:30	YES	18:30	
			18SEP2011	YES	7:30	YES	18:30	
			19SEP2011	YES	7:30	YES	18:30	
			20SEP2011	YES	7:30	YES	18:30	
			21SEP2011	YES	7:30	YES	18:30	
			22SEP2011	YES	7:30	YES	18:30	
			23SEP2011	YES	7:30	YES	18:30	
			24SEP2011	YES	7:30	YES	18:30	
			25SEP2011	YES	7:30	YES	18:30	
			26SEP2011	YES	7:30	YES	18:30	
			27SEP2011	YES	7:30	YES	18:30	
			28SEP2011	YES	7:30	YES	18:30	
			29SEP2011	YES	7:30	YES	18:30	
			30SEP2011	YES	7:30	YES	18:30	
			01OCT2011	YES	7:30	YES	18:30	
			02OCT2011	YES	7:40	YES	18:30	
			03OCT2011	YES	7:30	YES	18:30	
			04OCT2011	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	05OCT2011	YES	7:30	YES	18:30	
			06OCT2011	YES	7:30	YES	18:30	
			07OCT2011	YES	7:30	YES	18:30	
			08OCT2011	YES	7:30	YES	18:30	
			09OCT2011	YES	7:30	YES	18:00	
			10OCT2011	YES	7:30	YES	18:30	
			11OCT2011	YES	7:30	YES	18:30	
			12OCT2011	YES	7:30	YES	18:30	
			13OCT2011	YES	7:30	YES	18:30	
			14OCT2011	YES	7:30	YES	18:30	
			15OCT2011	YES	7:30	YES	18:30	
			16OCT2011	YES	7:30	YES	18:30	
			17OCT2011	YES	7:30	YES	18:30	
			18OCT2011	YES	7:30	YES	18:30	
			19OCT2011	YES	7:30	YES	18:30	
			20OCT2011	YES	7:30	YES	18:30	
			21OCT2011	YES	7:30	YES	18:00	
			22OCT2011	YES	7:30		18:30	
			23OCT2011	YES	7:30	YES	18:15	
			24OCT2011	YES	7:30	YES	18:30	
			25OCT2011	YES	7:30	YES	18:30	
			26OCT2011	YES	7:30	YES	18:30	
			27OCT2011	YES	7:30	YES	18:30	
			28OCT2011	YES	7:30	YES	18:40	
			29OCT2011	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	30OCT2011	YES	7:30	YES	18:00	
			31OCT2011	YES	7:30	YES	18:30	
			01NOV2011	YES	7:30	YES	18:30	
			02NOV2011	YES	7:30	YES	19:00	
			03NOV2011	YES	8:00	YES	18:45	
			04NOV2011	YES	8:00	YES	18:30	
			05NOV2011	YES	8:00	YES	18:00	
			06NOV2011	YES	8:00	YES	18:00	
			07NOV2011	YES	8:00	YES	18:15	
			08NOV2011	YES	8:00	YES	18:30	
			09NOV2011	YES	8:30	YES	18:30	
			10NOV2011	YES	8:00	YES	18:15	
			11NOV2011	YES	8:00	YES	18:15	
			12NOV2011	YES	8:30	YES	18:30	
			13NOV2011	YES	8:30	YES	18:00	
			14NOV2011	YES	8:00	YES	18:30	
			15NOV2011	YES	8:00	YES	18:30	
			16NOV2011	YES	7:30	YES	18:30	
			17NOV2011	YES	7:30	YES	18:30	
			18NOV2011	YES	7:30	YES	18:30	
			19NOV2011	YES	7:30	YES	18:30	
			20NOV2011	YES	7:30	YES	18:00	
			21NOV2011	YES	7:30	YES	18:30	
			22NOV2011	YES	7:30	YES	18:30	
			23NOV2011	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	058	1	24NOV2011	YES	7:30	YES	18:30	
			25NOV2011	YES	7:30	YES	18:30	
			26NOV2011	YES	8:00	YES	18:30	
			27NOV2011	YES	7:30	YES	18:00	
			28NOV2011	YES	7:30	YES	18:30	
			29NOV2011	YES	7:30	YES	18:30	
			30NOV2011	YES	7:30	YES	18:30	
			01DEC2011	YES	7:30	YES	18:30	
			02DEC2011	YES	7:30	YES	18:30	
			03DEC2011	YES	7:40	YES	18:30	
			04DEC2011		7:30	YES	18:30	
			05DEC2011	YES	7:30	YES	18:30	
			06DEC2011	YES	7:00	NO	18:30	
			07DEC2011	YES	7:30	YES	18:30	
			08DEC2011	YES	7:30	YES	18:30	
			09DEC2011	YES	7:30	YES	18:30	
			10DEC2011	YES	7:30	YES	18:30	
			11DEC2011	YES	7:30	YES	18:00	
			12DEC2011	YES	7:30	YES	18:30	
			13DEC2011	YES	7:30			
	059	1	29DEC2010			YES	18:20	
			30DEC2010	YES	7:30	YES	18:30	
			31DEC2010	YES	7:40	NO		vergessen
			01JAN2011	YES	8:35	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	02JAN2011	YES	7:40	YES	18:30	
			03JAN2011	YES	9:00	YES	18:10	
			04JAN2011	YES	7:00	YES	18:15	
			05JAN2011	YES	7:40	YES	18:40	
			06JAN2011	YES	8:00	YES	17:55	
			07JAN2011	YES	7:30	YES	20:30	
			08JAN2011	YES	8:10	YES	18:10	
			09JAN2011	YES	7:50	YES	18:00	
			10JAN2011	YES	7:30	YES	18:30	
			11JAN2011	YES	7:20	YES	18:30	
			12JAN2011	YES	7:15	YES	17:50	
			13JAN2011	YES	6:45	YES	18:30	
			14JAN2011	YES	6:35	YES	17:15	
			15JAN2011	YES	7:20	YES	20:00	
			16JAN2011	YES	7:20	YES	19:20	
			17JAN2011	YES	8:00	YES	18:40	
			18JAN2011	YES	6:45	YES	18:45	
			19JAN2011	YES	7:00	YES	18:25	
			20JAN2011	YES	7:10	YES	18:30	
			21JAN2011	YES	7:25			
			21JAN2011			YES	18:05	
			22JAN2011	YES	7:00	YES	18:05	
			23JAN2011	YES	8:40	YES	19:45	
			24JAN2011	YES	8:00	YES	17:55	
			25JAN2011	YES	7:00	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	26JAN2011	YES	7:30	YES	18:50	
			27JAN2011	YES	7:10	YES	17:55	
			28JAN2011	YES	7:30	YES	18:30	
			29JAN2011	YES	7:10	YES	18:30	
			30JAN2011	YES	8:00	YES	19:45	
			31JAN2011	YES	6:50	YES	18:15	
			01FEB2011	YES	6:50	YES	18:15	
			02FEB2011	YES	6:45	YES	18:10	
			03FEB2011	YES	6:40	NO		vergessen!
			04FEB2011	YES	7:00	YES	19:30	
			05FEB2011	YES	8:00	YES	18:15	
			06FEB2011	YES	8:30	YES	17:45	
			07FEB2011	YES	7:00	YES	18:30	
			08FEB2011	YES	8:00	YES	18:00	
			09FEB2011	YES	7:10	YES	18:30	
			10FEB2011	YES	8:00	YES	18:10	
			11FEB2011	YES	7:05	YES	18:05	
			12FEB2011	YES	7:15	YES	17:50	
			13FEB2011	YES	9:10	YES	18:00	
			14FEB2011	YES	7:55	NO		vergessen
			15FEB2011	YES	7:50	YES	17:40	
			16FEB2011	YES	8:00	YES	17:45	
			17FEB2011	YES	7:00	YES	18:20	
			18FEB2011	YES	7:45	YES	18:00	
			19FEB2011	YES	7:50	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	20FEB2011	YES	7:15	YES	17:15	vergessen
			21FEB2011	YES	8:55	YES	17:45	
			22FEB2011	YES	7:30	YES	18:15	
			23FEB2011	YES	7:20	YES	18:30	
			24FEB2011	YES	7:35	YES	18:15	
			25FEB2011	YES	7:10		18:25	
			26FEB2011	YES	6:40	NO		
			27FEB2011	YES	9:20	YES	18:40	
			28FEB2011	YES	6:55	YES	18:40	
			01MAR2011	YES	7:05	YES	18:10	
			02MAR2011	YES	6:45	YES	18:35	
			03MAR2011	YES	6:40	YES	18:20	
			04MAR2011	YES	7:15	YES	18:00	
			05MAR2011	YES	8:30	YES	18:30	
			06MAR2011	YES	8:25	YES	18:25	
			07MAR2011	YES	6:50	YES	19:25	
			08MAR2011	YES	8:25		17:25	
			09MAR2011	YES	7:40	YES	18:30	
			10MAR2011	YES	7:10	YES	18:20	
			11MAR2011	YES	6:50	YES	18:10	
			12MAR2011	YES	7:30	YES	18:50	
			13MAR2011	YES	7:35	YES	19:30	
			14MAR2011	YES	7:35		18:30	
			15MAR2011	YES	6:50	YES	18:20	
			16MAR2011	YES	7:30	YES	18:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	17MAR2011	YES	7:20	YES	18:30	
			18MAR2011	YES	7:15	YES	18:30	
			19MAR2011	YES	8:20	YES	18:40	
			20MAR2011	YES	7:20	YES	18:40	
			21MAR2011	YES	6:50	YES	18:10	
			22MAR2011	YES	7:10	YES	18:00	
			23MAR2011	YES	7:30	YES	18:30	
			24MAR2011	YES	7:00	YES	18:50	
			25MAR2011	YES	7:30	YES	18:10	
			26MAR2011	YES	6:35	YES	18:00	
			27MAR2011	YES	7:20	YES	18:35	
			28MAR2011	YES	7:00	YES	18:25	
			29MAR2011	YES	7:00	YES	18:20	
			30MAR2011	YES	8:05	YES	18:15	
			31MAR2011	YES	7:00			
			31MAR2011	YES		YES	18:15	
			01APR2011	YES	7:00	YES	18:35	
			02APR2011	YES	6:45	YES	18:00	
			03APR2011	YES	8:45	NO		verpasst
			04APR2011	YES	7:10	YES	18:10	
			05APR2011	YES	7:20	YES	18:30	
			06APR2011	YES	6:50	YES	18:30	
			07APR2011	YES	7:20	YES	17:50	
			08APR2011	YES	7:00	YES	18:30	
			09APR2011	YES	6:55	YES	15:50	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	10APR2011	YES	9:10	YES	19:05	
			11APR2011	YES	6:40	YES	18:40	
			12APR2011	YES	7:20	YES	18:00	
			13APR2011	YES	8:00	YES	18:45	
			14APR2011	YES	6:45	YES	17:50	
			15APR2011	YES	6:40	YES	17:40	
			16APR2011	YES	7:15	YES	20:10	
			17APR2011	YES	7:55	YES	18:25	
			18APR2011	YES	7:30	YES	18:30	
			19APR2011	YES	7:30	YES	18:20	
			20APR2011	YES	6:40	YES	18:15	
			21APR2011	YES	6:40	YES	18:15	
			22APR2011	YES	6:15	YES	18:40	
			23APR2011	YES	7:35	YES	19:00	
			24APR2011	YES	8:30	YES	18:40	
			25APR2011	YES	7:50	YES	17:05	
			26APR2011	YES	7:30	YES	17:10	
			27APR2011	YES	7:10	YES	17:30	
			28APR2011	YES	6:40	YES	17:45	
			29APR2011	YES	7:40	YES	18:30	
			30APR2011	YES	6:30	YES	17:35	
			01MAY2011	YES	7:00	YES	18:45	
			02MAY2011	YES	7:55	YES	18:45	
			03MAY2011	YES	7:10	YES	17:00	
			04MAY2011	YES	6:20	YES	18:25	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	05MAY2011	YES	6:30	YES	17:45	
			06MAY2011	YES	8:00	YES	18:40	
			07MAY2011	YES	6:10	YES	18:50	
			08MAY2011	YES	8:30	YES	18:30	
			09MAY2011	YES	7:20	YES	18:40	
			10MAY2011	YES	6:20	NO		verpasst
			11MAY2011	YES	7:45	YES	18:15	
			12MAY2011	YES	7:00	YES	18:25	
			13MAY2011	YES	6:40	YES	17:45	
			14MAY2011	YES	6:30	YES	18:20	
			15MAY2011	YES	7:00	YES	18:00	
			16MAY2011	YES	8:30	YES	17:10	
			17MAY2011	YES	8:30	YES	18:00	
			18MAY2011	YES	7:30	YES	18:05	
			19MAY2011	YES	7:50	YES	17:50	
			20MAY2011	YES	7:50	YES	18:30	
			21MAY2011	YES	7:35	YES	17:20	
			22MAY2011	YES	7:40	YES	18:40	
			23MAY2011	YES	7:15	YES	18:30	
			24MAY2011	YES	6:30			verpasst
			25MAY2011	YES	8:45	YES	18:50	
			26MAY2011	YES	5:50	YES	18:15	
			27MAY2011	YES	8:45	YES	18:10	
			28MAY2011	YES	7:40	YES	18:00	
			29MAY2011	YES	8:00	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	30MAY2011	YES	7:30	YES	18:10	
			31MAY2011	YES	6:10	YES	18:05	
			01JUN2011	YES	7:05	YES	18:25	
			02JUN2011	YES	7:15	YES	18:05	
			03JUN2011	YES	6:40	YES	18:25	
			04JUN2011	YES	6:50	YES	18:00	
			05JUN2011	YES	7:20	YES	18:05	
			06JUN2011	YES	6:40	YES	18:00	
			07JUN2011	YES	6:05			
			07JUN2011			YES	18:10	
			08JUN2011	YES	6:15	YES	18:00	
			09JUN2011	YES	8:05	YES	18:40	
			10JUN2011	YES	6:40	YES	18:00	
			11JUN2011	YES	6:50	YES	17:05	
			12JUN2011	YES	8:50	YES	18:00	
			13JUN2011	YES	8:25	YES	18:40	
			14JUN2011	YES	6:30	YES	18:10	
			15JUN2011	YES	7:50	YES	18:05	
			16JUN2011	YES	6:15	YES	18:10	
			17JUN2011	YES	7:20	YES	17:50	
			18JUN2011	YES	6:35	YES	18:20	
			19JUN2011	YES	7:30	YES	18:15	
			20JUN2011	YES	7:40	YES	18:10	
			21JUN2011	YES	6:50	YES	18:15	
			22JUN2011	YES	6:45	YES	18:40	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	23JUN2011	YES	8:35	YES	18:30	
			24JUN2011	YES	8:15	YES	18:05	
			25JUN2011	YES	8:05	YES	18:20	
			26JUN2011	YES	8:40	YES	18:00	
			27JUN2011	YES	7:45	YES	18:10	
			28JUN2011	YES	7:45	YES	18:25	
			29JUN2011	YES	8:35	YES	18:10	
			30JUN2011	YES	7:30	YES	18:50	
			01JUL2011	YES	7:30	YES	18:50	
			02JUL2011	YES	8:15	YES	18:20	
			03JUL2011	YES	8:10	YES	18:10	
			04JUL2011	YES	7:15	YES	18:10	
			05JUL2011	YES	8:00	YES	18:10	
			06JUL2011	YES	7:45	YES	18:20	
			07JUL2011	YES	7:15	YES	17:30	
			08JUL2011	YES	6:20	YES	18:20	
			09JUL2011	YES	8:10	NO		verpasst
			10JUL2011	YES	9:05	YES	18:05	
			11JUL2011	YES	7:25		11:10	
			12JUL2011	YES	8:15	NO		verpasst
			13JUL2011	YES	7:25	YES	18:10	
			14JUL2011	YES	6:40	YES	18:20	
			15JUL2011	YES	7:30	YES	18:10	
			16JUL2011	YES	7:31	YES	18:10	
			17JUL2011	YES	7:00	YES	18:55	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	18JUL2011	YES	7:30		18:05	
			19JUL2011	YES	6:40	YES	18:10	
			20JUL2011	YES	6:40	YES	18:20	
			21JUL2011	YES	7:25	YES	18:10	
			22JUL2011	YES	6:30	YES	18:00	
			23JUL2011	YES	7:20	YES	18:10	
			24JUL2011	YES	6:45	YES	18:20	
			25JUL2011	YES	7:20	YES	18:30	
			26JUL2011	YES	7:55	YES	18:20	
			27JUL2011	YES	6:30		18:00	
			28JUL2011	YES	6:45	YES	18:00	
			29JUL2011	YES	7:30	YES	18:10	
			30JUL2011	YES	7:45	YES	17:45	
			31JUL2011	YES	8:20	YES	18:20	
			01AUG2011	YES	8:25	YES	17:20	
			02AUG2011	YES	7:05	YES	18:10	
			03AUG2011	YES	7:15	YES	18:45	
			04AUG2011	YES	7:15	YES	18:20	
			05AUG2011	YES	6:55	YES	18:30	
			06AUG2011	YES	7:20	YES	18:35	
			07AUG2011	YES	8:10	YES	19:30	
			08AUG2011	YES	7:50	YES	18:00	
			09AUG2011	YES	8:05	NO		verpasst
			10AUG2011	YES	6:40	YES	18:15	
			11AUG2011	YES	7:50		18:20	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	12AUG2011	YES	7:15	NO		verpasst
			13AUG2011	YES	9:00	YES	18:00	
			14AUG2011	YES	7:10	YES	18:25	
			15AUG2011	YES	8:15	YES	18:35	
			16AUG2011	YES	7:10	YES	18:55	
			17AUG2011	YES	7:45	YES	18:00	
			18AUG2011	YES	7:45	YES	18:10	
			19AUG2011	YES	8:05	YES	18:10	
			20AUG2011	YES	7:50			Abends verpasst!
			21AUG2011	YES	7:40	YES	18:50	
			22AUG2011	YES	8:00	YES	18:00	
			23AUG2011	YES	7:20	YES	17:40	
			24AUG2011	YES	7:50		17:20	
			25AUG2011	YES	7:55	YES	17:55	
			26AUG2011	YES	7:15	YES	18:15	
			27AUG2011	YES	7:30	YES	18:15	
			28AUG2011	YES	8:00	YES	18:00	
			29AUG2011	YES	7:30	YES	18:30	
			30AUG2011	YES	9:00	YES	18:20	
			31AUG2011	YES	7:20	YES	19:10	
			01SEP2011	YES	7:35	NO		verpasst
			02SEP2011	YES	7:50	NO		
			03SEP2011	YES	7:50	YES	17:10	
			04SEP2011	YES	18:00	YES	18:30	
			05SEP2011	YES	8:10	YES	18:50	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	06SEP2011	YES	7:10	YES	18:00	
			07SEP2011	YES	7:20	YES	18:50	
			08SEP2011	YES	6:50			
			08SEP2011			YES	18:10	
			09SEP2011	YES	7:40	YES	17:45	
			10SEP2011	YES	7:00	YES	17:50	
			11SEP2011	YES	7:10	YES	18:10	
			12SEP2011	YES	6:45	YES	17:40	
			13SEP2011	YES	7:10	YES	18:45	
			14SEP2011	YES	6:45	YES	18:00	
			15SEP2011	YES	7:00	YES	18:50	
			16SEP2011	YES	7:30	YES	18:05	
			17SEP2011	YES	8:10	YES	17:30	
			18SEP2011	YES	8:20	YES	18:10	
			19SEP2011	YES	7:20	YES	18:20	
			20SEP2011	YES	7:20	YES	18:10	
			21SEP2011	YES	8:00	YES	18:00	
			22SEP2011	YES	8:00	YES	18:10	
			23SEP2011	YES	7:30	YES	17:45	
			24SEP2011	YES	7:30	YES	17:45	
			25SEP2011	YES	8:05	YES	18:55	
			26SEP2011	YES	7:45	YES	19:00	
			27SEP2011	YES	7:50	YES	18:55	
			28SEP2011	YES	7:15	YES	18:55	
			29SEP2011	YES	7:15	YES	17:55	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	30SEP2011	YES	7:00	YES	18:40	
			01OCT2011	YES	7:40	YES	18:05	
			02OCT2011	YES	7:45	YES	18:10	
			03OCT2011	YES	8:10	YES	18:00	
			04OCT2011	YES	6:25	NO		verpasst
			05OCT2011	YES	6:35	YES	18:00	
			06OCT2011	YES	7:50	NO		verpasst
			07OCT2011	YES	7:40	YES	18:25	
			08OCT2011	YES	7:00	YES	18:30	
			09OCT2011	YES	7:10	YES	18:50	
			10OCT2011	YES	8:15	YES	18:00	
			11OCT2011	YES	7:50	YES	20:15	
			12OCT2011	YES	7:50	YES	18:10	
			13OCT2011	YES	8:10	YES	18:15	
			14OCT2011	YES	7:30	YES	19:45	
			15OCT2011	YES	8:50	YES	18:00	
			16OCT2011	YES	7:10	YES	17:50	
			17OCT2011	YES	6:50	YES	18:05	
			18OCT2011	YES	7:25	YES	18:15	
			19OCT2011	YES	8:20	YES	18:45	
			20OCT2011	YES	7:15	YES	19:00	
			21OCT2011	YES	7:45	YES	19:45	
			22OCT2011	YES	7:35	YES	18:05	
			23OCT2011	YES	8:55	YES	18:40	
			24OCT2011	YES	8:25	YES	18:10	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	25OCT2011	YES	7:40	YES	18:00	
			26OCT2011	YES	8:10	YES	18:00	
			27OCT2011	YES	7:45	YES	19:10	
			28OCT2011	YES	7:30	YES	19:20	
			29OCT2011	YES	8:00	YES	19:10	
			30OCT2011	YES	7:40	YES	18:10	
			31OCT2011	YES	7:50	YES	18:25	
			01NOV2011	YES	7:00	YES	18:30	
			02NOV2011	YES	7:30	YES	18:45	
			03NOV2011	YES	7:20	YES	17:30	
			04NOV2011	YES	7:45	YES	18:30	
			05NOV2011	YES	7:45	YES	19:45	
			06NOV2011	YES	6:50	YES	19:55	
			07NOV2011	YES	8:30	NO		verpasst
			08NOV2011	YES	8:10	YES	18:05	
			09NOV2011	YES	8:40	YES	18:20	
			10NOV2011	YES	7:20	YES	19:15	
			11NOV2011	YES	8:05	YES	19:00	
			12NOV2011	YES	8:00	YES	17:50	
			13NOV2011	YES	8:00	YES	19:45	
			14NOV2011	YES	7:35	YES	17:45	
			15NOV2011	YES	7:10	YES	17:50	
			16NOV2011	YES	7:20	YES	18:00	
			17NOV2011	YES	7:15	NO		verpasst
			18NOV2011	YES	7:45	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	059	1	19NOV2011	YES	7:20	YES	19:00	
			20NOV2011	YES	7:30	YES	17:45	
			21NOV2011	YES	8:00	YES	17:50	
			22NOV2011	YES	9:05	YES	18:00	
			23NOV2011	YES	7:30	YES	18:00	
			24NOV2011	YES	8:25	YES	18:00	
			25NOV2011	YES	8:20	YES	17:45	
			26NOV2011	YES	8:40	YES	18:05	
			27NOV2011	YES	9:20	YES	18:00	
			28NOV2011	YES	7:00	YES	18:28	
			29NOV2011	YES	7:25	YES	17:30	
			30NOV2011	YES	7:20	YES	18:10	
			01DEC2011	YES	7:25	YES	17:50	
			02DEC2011	YES	6:05	YES	18:30	
			03DEC2011	YES	8:10	YES	20:15	
			04DEC2011	YES	8:20	NO		verpasst
			05DEC2011	YES	7:30	YES	18:15	
			06DEC2011	YES	8:15	YES	18:06	
			07DEC2011	YES	7:25	YES	18:00	
	065	16	31AUG2010	YES	8:28	YES	18:33	Am 30.08.2010 abends schon 1 eingenommen.
			01SEP2010	YES	8:29	YES	18:25	
			02SEP2010	YES	8:32	YES	18:30	
			03SEP2010	YES	8:35	YES	18:29	
			04SEP2010	YES	8:39	YES	18:26	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	065	16	05SEP2010	YES	8:27	YES	18:31	
			06SEP2010	YES	8:31	YES	18:30	
			07SEP2010	YES	8:30	YES	18:30	
			08SEP2010	YES	8:30	YES	18:30	
			09SEP2010	YES	8:30	YES	18:30	
			10SEP2010	YES	8:30	YES	18:30	
			11SEP2010	YES	8:30	YES	18:30	
			12SEP2010	YES	8:30	YES	18:30	
			13SEP2010	YES	8:30	YES	18:30	
			14SEP2010	YES	8:30	YES	18:30	
			15SEP2010	YES	8:30	YES	18:30	
			16SEP2010	YES	8:30	YES	18:30	
			17SEP2010	YES	8:30	YES	18:30	
			18SEP2010	YES	8:30	YES	18:30	
			19SEP2010	YES	8:30	YES	18:30	
			20SEP2010	YES	8:30	YES	18:30	
			21SEP2010	YES	8:30	YES	18:30	
			22SEP2010	YES	8:30	YES	18:30	
			23SEP2010	YES	8:30	YES	18:30	
			24SEP2010	YES	8:30	YES	18:30	
			25SEP2010	YES	8:30	YES	18:30	
			26SEP2010	YES	8:30	YES	18:30	
			27SEP2010	YES	8:30			
			27SEP2010	YES	8:30	YES	18:30	
			28SEP2010	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	065	16	29SEP2010	YES	8:30	YES	18:30	
			30SEP2010	YES	8:30	YES	18:30	
			01OCT2010	YES	8:30	YES	18:30	
			02OCT2010	YES	8:30	YES	18:30	
			03OCT2010	YES	8:30	YES	18:30	
			04OCT2010	YES	8:30	YES	18:30	
			05OCT2010	YES	8:30	YES	18:30	
			06OCT2010	YES	8:30	YES	18:30	
			07OCT2010	YES	8:30	YES	18:30	
			08OCT2010	YES	8:30	YES	18:30	
			09OCT2010	YES	8:30	YES	18:30	
			10OCT2010	YES	8:30	YES	18:30	
			11OCT2010	YES	8:30	YES	18:30	
			12OCT2010	YES	8:30	YES	18:30	
			13OCT2010	YES	8:30	YES	18:30	
			14OCT2010	YES	8:30	YES	18:30	
			15OCT2010	YES	8:30	YES	18:30	
			16OCT2010	YES	8:30	YES	18:30	
			17OCT2010	YES	8:30	YES	18:30	
			18OCT2010	YES	8:30	YES	18:30	
			19OCT2010	YES	8:30	YES	18:30	
			20OCT2010	YES	8:30	YES	18:30	
			21OCT2010	YES	8:30	YES	18:30	
			22OCT2010	YES	8:30	YES	18:30	
			23OCT2010	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	065	16	24OCT2010	YES	8:30	YES	18:30	
			25OCT2010	YES	8:30	YES	18:30	Montag
			26OCT2010	YES	8:30	YES	18:30	
			27OCT2010	YES	8:30	YES	18:30	
			28OCT2010	YES	8:30	YES	17:30	
			29OCT2010	YES	8:30	YES	18:30	
			30OCT2010	YES	8:30	YES	18:30	
			31OCT2010	YES	8:30	YES	18:30	
			01NOV2010	YES	8:30	YES	18:30	Montag
			02NOV2010	YES	8:30	YES	18:30	
			03NOV2010	YES	8:30	YES	18:30	
			04NOV2010	YES	8:30	YES	18:30	
			05NOV2010	YES	8:30	YES	18:30	
			06NOV2010	YES	8:30	YES	18:30	
			07NOV2010	YES	8:30	YES	18:30	
			08NOV2010	YES	8:30	YES	18:30	Montag
			09NOV2010	YES	8:30	YES	18:30	Di
			10NOV2010	YES	8:30	YES	18:30	Mi
			11NOV2010	YES	8:30	YES	18:30	Do
			12NOV2010	YES	8:30	YES	18:30	Fr
			13NOV2010	YES	8:30	YES	18:30	Sa
			14NOV2010	YES	8:30	YES	18:30	So
			15NOV2010	YES	8:30	YES	18:30	Montag
			16NOV2010	YES	8:30	YES	18:30	Di
			17NOV2010	YES	8:30	YES	18:30	Mi

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	065	16	18NOV2010	YES	8:30	YES	18:30	Do
			19NOV2010	YES	8:30	YES	18:30	Fr.
			20NOV2010	YES	8:30	YES	18:30	Sa
			21NOV2010	YES	8:30	YES	18:30	So
			22NOV2010	YES	8:30	YES	18:30	Montag
			22NOV2010			YES	18:30	22.11. Montag
			23NOV2010					Di
			23NOV2010	YES	8:30	YES	18:30	Dienstag
			24NOV2010					Mi
			24NOV2010	YES	8:30	YES	18:30	Mi
			25NOV2010					Do
			25NOV2010	YES	8:30	YES	18:30	Do
			26NOV2010					Fr
			26NOV2010	YES	8:30	YES	18:30	Fr
			27NOV2010					Sa
			27NOV2010	YES	8:30	YES	18:30	Sa
			28NOV2010					So
			28NOV2010	YES	8:30	YES	18:30	So
			29NOV2010					Montag
			29NOV2010	YES	8:30	YES	18:30	Montag
			30NOV2010					Die
			30NOV2010	YES	8:30	YES	18:30	Di
			01DEC2010					Mi
			01DEC2010	YES	8:30	YES	18:30	Mittwoch
			02DEC2010					Do

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	065	16	02DEC2010	YES	8:30	YES	18:30	Do
			03DEC2010					Fr.
			03DEC2010	YES	8:30	YES	18:30	Fr
			04DEC2010					Sa
			04DEC2010	YES	8:30	YES	18:30	Sa
			05DEC2010					So
			05DEC2010	YES	8:30	YES	18:30	So
			06DEC2010					Montag
			06DEC2010	YES	8:30	YES	18:30	Montag
			07DEC2010					Die
			07DEC2010	YES	8:30	YES	18:30	Die
			08DEC2010	YES	8:30	YES	18:30	Mi
			09DEC2010	YES	8:30	YES	18:30	Do
			10DEC2010	YES	8:30	YES	18:30	
			11DEC2010	YES	8:30	YES	18:30	
			12DEC2010	YES	8:30	YES	18:30	
			13DEC2010	YES	8:30	YES	18:30	
			14DEC2010	YES	8:30	YES	18:30	
			15DEC2010	YES	8:30	YES	18:30	
			16DEC2010	YES	8:30	YES	18:30	
			17DEC2010	YES	8:30	YES	18:30	
			18DEC2010	YES	8:30	YES	18:30	
			19DEC2010	YES	8:30	YES	18:30	
			20DEC2010	YES	8:30	YES	18:30	
			21DEC2010	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	065	16	22DEC2010	YES	8:30	YES	18:30	
			23DEC2010	YES	8:30	YES	18:30	
			24DEC2010	YES	8:30	YES	18:30	
			25DEC2010	YES	8:30	YES	18:30	
			26DEC2010	YES	8:30	YES	18:30	
			27DEC2010	YES	8:30	YES	18:30	
			28DEC2010	YES	8:30	YES	18:30	
			29DEC2010	YES	8:30	YES	18:30	
			30DEC2010	YES	8:30	YES	18:30	
			31DEC2010	YES	8:30	YES	18:30	
			01JAN2011	YES	8:30	YES	18:30	
			02JAN2011	YES	8:30	YES	18:30	
			03JAN2011	YES	8:30	YES	18:30	
			04JAN2011	YES	8:30	YES	18:30	
			05JAN2011	YES	8:30	YES	18:30	
			06JAN2011	YES	8:30	YES	18:30	
			07JAN2011	YES	8:30	YES	18:30	
			08JAN2011	YES	8:30	YES	18:30	
			09JAN2011	YES	8:30	YES	18:30	
			10JAN2011	YES	8:30	YES	18:30	
			11JAN2011	YES	8:30	YES	18:30	
			12JAN2011	YES	8:30	YES	18:30	
			13JAN2011	YES	8:30	YES	18:30	
			14JAN2011	YES	8:30	YES	18:30	
			15JAN2011	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	065	16	16JAN2011	YES	8:30	YES	18:30	
			17JAN2011	YES	8:30			
	068	16		YES	9:30	YES	19:00	31/09/2011
			23NOV2010	YES	10:15	YES	18:00	
			24NOV2010	YES	8:30	YES	19:00	
			25NOV2010	YES	8:30	YES	18:30	
			26NOV2010	YES	9:00	YES	19:00	
			27NOV2010	YES	8:00	YES	19:00	
			28NOV2010	YES	8:30	YES	18:30	
			29NOV2010	YES	9:00	NO		vergessen, ich hatte Migräne
			30NOV2010	YES	6:00	YES	21:30	
			01DEC2010	YES	9:00	NO		vergessen
			02DEC2010	YES	8:30	YES	19:00	
			03DEC2010	YES	8:30	YES	18:30	
			04DEC2010	YES	9:00	YES	20:00	
			05DEC2010	YES	8:30	YES	18:30	
			06DEC2010	YES	8:00	YES	17:00	
			07DEC2010	YES	8:30	YES	18:00	
			08DEC2010	YES	8:30	YES	18:30	
			09DEC2010	YES	8:30	YES	18:30	
			10DEC2010	YES	9:00	YES	18:00	
			11DEC2010	YES	8:00	NO		vergessen
			12DEC2010	YES	8:30	YES	21:00	
			13DEC2010	YES	8:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	14DEC2010	YES	9:00	YES	19:45	
			15DEC2010	YES	9:00	YES	22:00	
			16DEC2010	YES	8:30	YES	18:00	
			17DEC2010	YES	8:00	YES	17:30	
			18DEC2010	YES	8:30	YES	19:00	
			19DEC2010	YES	8:30	YES	17:00	
			20DEC2010	YES	7:30			
			20DEC2010	YES	7:30	YES	18:00	
			21DEC2010	YES	8:00	YES	18:00	
			22DEC2010	YES	8:00	YES	18:00	
			23DEC2010	YES	8:00	YES	19:00	
			24DEC2010	YES	8:00	YES	18:00	
			25DEC2010	YES	9:00	YES	21:00	
			26DEC2010	YES	9:00	YES	18:45	
			27DEC2010	YES	9:00	YES	19:30	
			28DEC2010	YES	9:00	YES	19:00	
			29DEC2010	YES	8:30	YES	18:00	
			30DEC2010	YES	7:15		18:30	
			31DEC2010	YES	9:30	YES	18:30	
			01JAN2011	YES	9:30	YES	18:00	
			02JAN2011	YES	8:00	YES	18:00	
			03JAN2011	YES	10:00	YES	18:00	
			04JAN2011	YES	10:00	YES	17:00	
			05JAN2011	YES	9:30	YES	19:30	
			06JAN2011	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	07JAN2011	YES	10:00	YES	17:30	
			08JAN2011	YES	9:00	YES	19:30	
			09JAN2011	YES	9:30	YES	18:00	
			10JAN2011	YES	9:30	YES	17:30	
			11JAN2011	YES	7:45	YES	18:30	
			12JAN2011	YES	7:00	YES	18:30	
			13JAN2011	YES	8:30	YES	17:00	
			14JAN2011	YES	10:00	YES	17:00	
			15JAN2011	YES	8:30	YES	19:00	
			16JAN2011	YES	10:00	YES	16:30	
			17JAN2011	YES	6:30	YES	18:30	
			18JAN2011	YES	8:45	YES	18:30	
			19JAN2011	YES	9:00	YES	19:00	
			20JAN2011	YES	7:00	YES	19:00	
			21JAN2011	YES	7:00	YES	17:30	
			22JAN2011	YES	8:30	YES	21:00	
			23JAN2011	YES	9:30	YES	17:30	
			24JAN2011	YES	9:00	YES	17:00	
			25JAN2011	YES	9:30	YES	17:30	
			26JAN2011	YES	9:00	YES	18:30	
			27JAN2011	YES	9:00			
			28JAN2011	YES	9:00	YES	19:00	
			29JAN2011	YES	9:30	YES	19:00	
			30JAN2011	YES	9:30	YES	16:30	
			31JAN2011	YES	9:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	01FEB2011	YES	9:00	YES	22:00	
			02FEB2011	YES	7:00	YES	19:00	
			03FEB2011	YES	6:00	YES	18:00	
			04FEB2011	YES	8:00	YES	18:00	
			05FEB2011	YES	9:30	YES	18:00	
			06FEB2011	YES	9:30	YES	20:00	
			07FEB2011	YES	8:30	YES	20:30	
			08FEB2011	YES	9:00	YES	19:00	
			09FEB2011	YES	9:00	YES	19:00	
			10FEB2011	YES	7:15			
			10FEB2011	YES	8:00	YES	18:00	
			11FEB2011	YES	8:30	YES	18:30	
			12FEB2011	YES	8:30	YES	18:30	
			13FEB2011	YES	9:00	YES	19:00	
			14FEB2011	YES	9:00	YES	18:30	
			15FEB2011	YES	8:30	YES	19:00	
			16FEB2011	YES	8:30	YES	21:00	
			17FEB2011	YES	9:00	YES	21:00	
			18FEB2011	YES	8:00	YES	17:30	
			19FEB2011	YES	10:00	YES	19:00	
			20FEB2011	YES	9:00	YES	20:30	
			21FEB2011	YES	9:00	YES	19:00	
			22FEB2011	YES	8:00	YES	19:00	
			23FEB2011	YES	9:00	YES	19:00	
			24FEB2011	YES	8:15	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	25FEB2011	YES	8:30	YES	19:00	
			26FEB2011	YES	8:45	YES	21:00	
			27FEB2011	YES	8:00	YES	19:00	
			28FEB2011	YES	8:00	YES	18:00	
			01MAR2011	YES	8:00	YES	19:00	
			02MAR2011	YES	7:00	YES	18:00	
			03MAR2011	YES	8:00	YES	19:00	
			04MAR2011	YES	8:00	YES	18:00	
			05MAR2011	YES	8:30	YES	19:30	
			06MAR2011	YES	8:00	YES	18:00	
			07MAR2011	YES	8:30	YES	18:00	
			08MAR2011	YES	8:45	YES	19:00	
			09MAR2011	YES	8:00	YES	19:00	
			10MAR2011	YES	8:00	YES	19:00	
			11MAR2011	YES	7:45	YES	18:45	
			12MAR2011	YES	8:00	YES	23:00	
			13MAR2011	YES	9:00	YES	23:00	
			14MAR2011	YES	9:00	YES	18:30	
			15MAR2011	YES	8:45	YES	19:00	
			16MAR2011	YES	8:00	YES	19:00	
			17MAR2011	YES	8:30	YES	19:00	
			18MAR2011	YES	8:00	YES	19:30	
			19MAR2011	YES	8:00	YES	18:00	
			20MAR2011	YES	9:00	YES	19:00	
			21MAR2011	YES	7:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	22MAR2011	YES	8:00	YES	18:00	
			23MAR2011	YES	8:30	YES	22:00	
			24MAR2011	YES	8:00	YES	19:00	
			25MAR2011	YES	8:00	YES	17:00	
			26MAR2011	YES	8:00	YES	18:00	
			27MAR2011	YES	8:00	YES	19:00	
			28MAR2011	YES	8:00	YES	19:00	
			29MAR2011	YES	8:00	YES	20:00	
			30MAR2011	YES	8:00	YES	19:00	
			31MAR2011	YES	8:30	YES	19:00	
			01APR2011	YES	8:30	YES	19:00	
			02APR2011	YES	8:00	YES	20:00	
			03APR2011	YES	8:45	YES	19:45	
			04APR2011	YES	6:30	YES	17:00	
			05APR2011	YES	8:00	YES	18:00	
			06APR2011	YES	8:30	YES	21:00	
			07APR2011	YES	7:30	YES	19:00	
			08APR2011	YES	8:30	YES	19:00	
			09APR2011	YES	8:30	YES	19:30	
			10APR2011	YES	8:30	YES	19:00	
			11APR2011	YES	8:00		20:00	
			12APR2011	YES	8:00	YES	19:00	
			13APR2011	YES	8:00	YES	18:00	
			14APR2011	YES	8:30	YES	19:30	
			15APR2011	YES	6:45	YES	19:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	16APR2011	YES	8:45		18:45	
			17APR2011	YES	8:30	YES	19:30	
			18APR2011	YES	8:00	YES	19:00	
			19APR2011	YES	9:00	YES	17:00	
			20APR2011	YES	8:00	YES	18:00	
			21APR2011	YES	8:00	YES	18:00	
			22APR2011	YES	9:00		19:00	
			23APR2011	YES	9:00	YES	17:40	
			24APR2011	YES	8:15	YES	19:15	
			25APR2011	YES	9:00	YES	19:30	
			26APR2011	YES	7:00	YES	18:00	
			27APR2011	YES	8:15	YES	20:00	
			28APR2011	YES	9:00	YES	19:00	
			29APR2011	YES	7:45	YES	18:00	
			30APR2011	YES	8:00	YES	18:00	
			01MAY2011	YES	7:30	YES	17:40	
			02MAY2011	YES	9:00	YES	19:00	
			03MAY2011	YES	10:00	YES	19:00	
			04MAY2011	YES	8:00	YES	19:00	
			05MAY2011	YES	8:00	YES	19:00	
			06MAY2011	YES	8:30	YES	19:00	
			07MAY2011	YES	8:00	YES	19:00	
			08MAY2011	YES	8:30	YES	19:30	
			09MAY2011	YES	8:00	YES	19:00	
			10MAY2011	YES	8:30	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	11MAY2011	YES	10:00	YES	19:00	
			12MAY2011	YES	8:30	YES	18:30	
			13MAY2011	YES	7:30	YES	19:00	
			14MAY2011	YES	9:00	YES	18:30	
			15MAY2011	YES	9:00	YES	18:30	
			16MAY2011	YES	9:00	YES	18:30	
			17MAY2011	YES	7:30	YES	19:00	
			18MAY2011	YES	8:00	YES	18:30	
			19MAY2011	YES	9:00	YES	19:00	
			20MAY2011	YES	9:00	YES	19:00	
			21MAY2011	YES	8:00	YES	21:00	
			22MAY2011	YES	8:00	YES	20:00	
			23MAY2011	YES	8:00	YES	19:00	
			24MAY2011	YES	8:00	YES	19:00	
			25MAY2011	YES	9:00	YES	19:00	
			26MAY2011	YES	9:00	YES	18:00	
			27MAY2011	YES	9:00	YES	18:00	
			28MAY2011	YES	8:30	YES	18:00	
			29MAY2011	YES	8:30	YES	18:00	
			30MAY2011	YES	8:00	YES	18:00	
			31MAY2011	YES	8:30	YES	19:00	
			01JUN2011	YES	8:30	YES	19:00	
			02JUN2011	YES	7:30	YES	18:30	
			03JUN2011	YES	8:00	YES	18:00	
			04JUN2011	YES	8:30	YES	18:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	05JUN2011	YES	8:30	YES	18:00	
			06JUN2011	YES	9:00	YES	18:00	
			07JUN2011	YES	9:30	YES	18:30	
			08JUN2011	YES	9:00	YES	18:00	
			09JUN2011	YES	8:00	YES	18:00	
			10JUN2011	YES	8:00	YES	17:30	
			11JUN2011	YES	6:30	YES	18:00	
			12JUN2011	YES	8:00	YES	18:00	
			13JUN2011	YES	7:45	YES	18:45	
			14JUN2011	YES	9:00	YES	18:00	
			15JUN2011	YES	8:30	YES	19:00	
			16JUN2011	YES	7:40	YES	19:00	
			17JUN2011	YES	7:15	YES	19:00	
			18JUN2011	YES	8:00	YES	19:00	
			19JUN2011	YES	8:00	YES	21:00	
			20JUN2011	YES	8:30	YES	18:00	
			21JUN2011	YES	8:30	YES	18:30	
			22JUN2011	YES	9:00		18:30	
			23JUN2011	YES	9:00		19:00	
			24JUN2011	YES	8:15	YES	19:00	
			25JUN2011	YES	9:00	YES	19:00	
			26JUN2011	YES	8:00	YES	18:30	
			27JUN2011	YES	7:30	YES	18:30	
			28JUN2011	YES	8:00	YES	19:30	
			29JUN2011	YES	9:00	YES	19:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	30JUN2011	YES	9:00	YES	18:30	
			01JUL2011	YES	9:00	YES	19:00	
			02JUL2011	YES	9:00	YES	18:30	
			03JUL2011	YES	9:00	YES	18:00	
			04JUL2011	YES	8:30	YES	19:00	
			05JUL2011	YES	8:30	YES	19:00	
			06JUL2011	YES	9:00	YES	18:30	
			07JUL2011	YES	9:00	YES	18:30	
			08JUL2011	YES	9:00	YES	18:30	
			09JUL2011	YES	9:00	YES	18:30	
			10JUL2011	YES	9:00	YES	20:00	
			11JUL2011	YES	9:00	YES	19:00	
			12JUL2011	YES	9:00	YES	19:00	
			13JUL2011	YES	9:00	YES	18:30	
			14JUL2011	YES	8:30	YES	19:00	
			15JUL2011	YES	8:45	YES		
			16JUL2011	YES	9:00	YES	19:00	
			17JUL2011	YES	8:30			
			18JUL2011	YES	9:30	YES	19:00	
			19JUL2011	YES	8:30	YES	19:00	
			20JUL2011	YES	8:00	YES	19:00	
			21JUL2011	YES	9:00	YES	19:30	
			22JUL2011	YES	9:00	YES	18:30	
			23JUL2011	YES	9:00	YES	18:30	
			24JUL2011	YES	9:30	YES	20:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	25JUL2011	YES	8:30	YES	19:00	
			26JUL2011	YES	9:00	YES	19:00	
			27JUL2011	YES	10:00	YES	19:00	
			28JUL2011	YES	9:00	YES	19:00	
			29JUL2011	YES	9:00	YES	19:00	
			30JUL2011	YES	8:30	YES	19:30	
			31JUL2011	YES	9:00	YES	20:00	
			01AUG2011	YES	8:00	YES	19:00	
			02AUG2011	YES	8:00	YES	19:00	
			03AUG2011	YES	9:00	YES	20:00	
			04AUG2011	YES	8:30	YES	22:00	
			05AUG2011	YES	9:30	YES	21:00	
			06AUG2011	YES	9:00	YES	21:30	
			07AUG2011	YES	9:00	YES	19:30	
			08AUG2011	YES	9:00	YES	19:00	
			09AUG2011	YES	8:15			
			09AUG2011	YES	9:30	YES	18:30	
			10AUG2011	YES	9:00	YES	19:00	
			11AUG2011	YES	12:00	YES	18:30	
			12AUG2011	YES	8:30		18:30	
			13AUG2011	YES	9:00	YES	19:00	
			14AUG2011	YES	9:30	YES	21:30	
			15AUG2011	YES	10:30	YES	21:00	
			16AUG2011	YES	10:00	YES	20:30	
			17AUG2011	YES	9:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	18AUG2011	YES	9:30	YES	19:00	
			19AUG2011	YES	9:00	YES	18:30	
			20AUG2011	YES	9:30	YES	19:00	
			21AUG2011	YES	9:00	YES	18:30	
			22AUG2011	YES	9:30	YES	19:00	
			23AUG2011	YES	9:00	YES	20:00	
			24AUG2011	YES	9:00	YES	19:00	
			25AUG2011	YES	10:00	YES	18:30	
			26AUG2011	YES	9:00	YES	18:30	
			27AUG2011	YES	9:00	YES	19:30	
			28AUG2011	YES	9:00	YES	19:30	
			29AUG2011	YES	9:00	YES	19:00	
			30AUG2011	YES	9:30	YES	19:00	
			31AUG2011	YES	10:00	YES	19:00	
			01SEP2011	YES	10:00	YES	20:00	
			02SEP2011	YES	9:30	YES	19:00	
			03SEP2011	YES	9:00	YES	19:00	
			04SEP2011	YES	9:30	YES	20:00	
			05SEP2011	YES	9:00	YES	19:30	
			06SEP2011	YES	8:30	YES	19:00	
			07SEP2011	YES	8:30	YES	19:00	
			08SEP2011	YES	9:00	YES	19:30	
			09SEP2011	YES	10:00	YES	19:00	
			10SEP2011	YES	9:00	YES	19:00	
			11SEP2011	YES	9:30	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	12SEP2011	YES	9:30	YES	19:00	
			13SEP2011	YES	9:30	YES	19:00	
			14SEP2011	YES	9:00	YES	19:00	
			15SEP2011	YES	9:00	YES	19:00	
			16SEP2011	YES	9:30	YES	19:30	
			17SEP2011	YES	9:30	YES	19:00	
			18SEP2011	YES	9:00	YES	19:00	
			19SEP2011	YES	10:00	YES	19:30	
			20SEP2011	YES	9:00	YES	19:00	
			21SEP2011	YES	9:00	YES	19:00	
			22SEP2011	YES	10:30	YES	19:00	
			23SEP2011	YES	9:00	YES	19:00	
			24SEP2011	YES	9:30	YES	19:15	
			25SEP2011	YES	9:30	YES	19:00	
			26SEP2011	YES	10:00	YES	19:30	
			27SEP2011	YES	9:30	YES	19:30	
			28SEP2011	YES	9:15	YES	20:00	
			29SEP2011	YES	9:30	YES	19:30	
			30SEP2011	YES	9:00	YES	19:30	
			01OCT2011	YES	10:00	YES	19:00	
			02OCT2011	YES	9:00	YES	19:00	
			03OCT2011	YES	9:00	YES	19:00	
			04OCT2011	YES	9:30	YES	19:00	
			05OCT2011	YES	9:30	YES	19:30	
			06OCT2011	YES	9:30	YES	19:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	07OCT2011	YES	10:00	YES	20:00	
			08OCT2011	YES	10:30	YES	20:00	
			09OCT2011	YES	10:00	YES	19:30	
			10OCT2011	YES	9:30	YES	19:00	
			11OCT2011	YES	9:00	YES	19:00	
			12OCT2011	YES	9:30	YES	19:30	
			13OCT2011	YES	9:00	YES	19:00	
			14OCT2011	YES	9:00	YES	20:00	
			15OCT2011	YES	9:30		19:30	
			16OCT2011	YES	9:30	YES	19:00	
			17OCT2011	YES	9:30	YES	19:30	
			18OCT2011	YES	9:30	YES	20:00	
			19OCT2011	YES	9:30	YES	19:30	
			20OCT2011	YES	11:00	YES	19:30	
			21OCT2011	YES	10:00	YES	19:30	
			22OCT2011	YES	10:00	YES	19:30	
			23OCT2011	YES	10:00	YES	20:00	
			24OCT2011	YES	9:30	YES	19:00	
			25OCT2011	YES	10:30	YES	19:30	
			26OCT2011	YES	10:00	YES	19:30	
			27OCT2011	YES	10:00	YES	19:30	
			28OCT2011	YES	10:00	YES	19:30	
			29OCT2011	YES	9:00	YES	20:00	
			30OCT2011	YES	10:30	YES	20:00	
			31OCT2011	YES	10:00	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	01NOV2011	YES	7:20		20:00	
			02NOV2011	YES	8:00	YES	20:00	
			03NOV2011	YES	8:30	YES	20:00	
			04NOV2011	YES	8:50	YES	20:45	
			05NOV2011	YES	8:30	YES	20:00	
			06NOV2011	YES	9:00	YES	20:00	
			07NOV2011	YES	10:00	YES	20:00	
			08NOV2011	YES	9:00	YES	20:00	
			09NOV2011	YES	9:00	YES	19:00	
			10NOV2011	YES	8:45	YES	19:00	
			11NOV2011	YES	10:00	YES	19:00	
			12NOV2011	YES	9:30	YES	18:00	
			13NOV2011	YES	9:30	YES	19:00	
			14NOV2011	YES	9:30	YES	19:00	
			15NOV2011	YES	12:00	YES	19:00	
			16NOV2011	YES	9:00	YES	19:00	
			17NOV2011	YES	9:00	YES	19:00	
			18NOV2011	YES	9:00	YES	19:00	
			19NOV2011	YES	11:00	YES	19:00	
			20NOV2011	YES	9:30	YES	19:30	
			21NOV2011	YES	9:00	YES	21:00	
			22NOV2011	YES	10:00	YES	20:00	
			23NOV2011	YES	10:00	YES	19:30	
			24NOV2011	YES	10:30	YES	20:00	
			25NOV2011	YES	10:00	YES	19:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	068	16	26NOV2011	YES	10:00	YES	19:00	
			27NOV2011	YES	10:00		19:30	
			28NOV2011	YES	10:00		19:30	
			29NOV2011	YES	10:00		20:00	
			30NOV2011	YES	10:00	YES	19:30	
			01DEC2011	YES	10:45		19:30	
			02DEC2011	YES	10:30	YES	19:30	
			03DEC2011	YES	10:30	YES	19:30	
			04DEC2011	YES	10:00	YES	20:00	
			05DEC2011	YES	10:00	YES	19:30	
			06DEC2011	YES	9:30	YES	19:30	
			07DEC2011	YES	9:30	YES	19:30	
			08DEC2011	YES	9:30	YES	20:00	
			09DEC2011	YES	10:00	YES	19:30	
			10DEC2011	YES	10:00	YES	19:30	
			11DEC2011	YES	10:00	YES	20:00	
	069	23	08DEC2010	YES	7:30	YES	17:45	
			09DEC2010	YES	6:00	YES	17:45	
			10DEC2010	YES	6:30	YES	18:00	
			11DEC2010	YES	7:30	YES	17:00	
			12DEC2010	YES	6:45	YES	17:15	
			13DEC2010	YES	6:30	YES	17:30	
			14DEC2010	YES	6:30	YES	18:00	
			15DEC2010	YES	6:30	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	16DEC2010	YES	6:30	YES	17:00	
			17DEC2010	YES	6:30	YES	17:00	
			18DEC2010	YES	7:30	YES	17:30	
			19DEC2010	YES	7:00	YES	17:00	
			20DEC2010	YES	6:30	YES	17:00	
			21DEC2010	YES	5:30	YES	17:00	
			22DEC2010	YES	7:45	YES	17:00	
			23DEC2010	YES	6:30	YES	17:00	
			24DEC2010	YES	6:30	YES	17:00	
			25DEC2010	YES	6:30	YES	17:00	
			26DEC2010	YES	7:30	YES	17:30	
			27DEC2010	YES	7:30	YES	17:00	
			28DEC2010	YES	6:30	YES	17:00	
			29DEC2010	YES	6:30	YES	17:00	
			30DEC2010	YES	6:30	YES	17:00	
			31DEC2010	YES	7:30	YES	17:00	
			01JAN2011	YES	7:00	YES	17:10	
			02JAN2011	YES	7:00	YES	17:00	
			03JAN2011	YES	7:00	YES	17:00	
			04JAN2011	YES	7:00	YES	17:30	
			05JAN2011	YES	6:30	YES	17:30	
			06JAN2011	YES	7:00	YES	17:00	
			07JAN2011	YES	7:00	YES	17:00	
			08JAN2011	YES	7:00	YES	17:00	
			09JAN2011	YES	7:00	YES	17:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	10JAN2011	YES	7:00	YES	17:00	
			11JAN2011	YES	7:00	YES	17:00	
			12JAN2011	YES	12:00	YES	17:15	
			13JAN2011	YES	6:30	YES	16:30	
			14JAN2011	YES	7:00	YES	17:30	
			15JAN2011	YES	7:00	YES	17:00	
			16JAN2011	YES	6:30	YES	19:00	
			17JAN2011	YES	7:00	YES	18:15	
			18JAN2011	YES	6:45	YES	17:10	
			19JAN2011	YES	7:00	YES	16:15	
			20JAN2011	YES	6:30	YES	17:00	
			21JAN2011	YES	7:00	YES	17:00	
			22JAN2011	YES	6:45	YES	17:00	
			23JAN2011	YES	7:15	YES	17:00	
			24JAN2011	YES	7:00	YES	17:00	
			25JAN2011	YES	7:00	YES	17:00	
			26JAN2011	YES	7:00	YES	17:30	
			27JAN2011	YES	7:00	YES	17:00	
			28JAN2011	YES	7:00	YES	17:15	
			29JAN2011	YES	7:00	YES	17:00	
			30JAN2011	YES	6:30	YES	17:00	
			31JAN2011	YES	7:00	YES	18:30	
			01FEB2011	YES	7:00	YES	17:00	
			02FEB2011	YES	7:00	YES	17:15	
			03FEB2011	YES	7:00	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	04FEB2011	YES	7:00	YES	17:00	
			05FEB2011	YES	7:15	YES	17:00	
			06FEB2011	YES	7:00	YES	17:00	
			07FEB2011	YES	6:30	YES	17:00	
			08FEB2011	YES	6:15	YES	17:00	
			09FEB2011	YES	7:00	YES	17:00	
			10FEB2011	YES	7:00	YES	17:00	
			11FEB2011	YES	7:00	YES	17:00	
			12FEB2011	YES	7:00	YES	17:00	
			13FEB2011	YES	7:15	YES	17:00	
			14FEB2011	YES	7:00	YES	17:00	
			15FEB2011	YES	7:00	YES	18:00	
			16FEB2011	YES	7:00	YES	17:00	
			17FEB2011	YES	7:10	YES	17:30	
			18FEB2011	YES	7:00	YES	17:45	
			19FEB2011	YES	7:30	YES	17:30	
			20FEB2011	YES	7:15	YES	17:10	
			21FEB2011	YES	7:00	YES	17:00	
			22FEB2011	YES	7:00	YES	17:10	
			23FEB2011	YES	6:45	YES	17:00	
			24FEB2011	YES	6:30	YES	17:00	
			25FEB2011	YES	7:00	YES	17:15	
			26FEB2011	YES	7:00	YES	17:00	
			27FEB2011	YES	7:00	YES	17:00	
			28FEB2011	YES	7:00	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	01MAR2011	YES	7:00	YES	17:00	
			02MAR2011	YES	7:00	YES	17:30	
			03MAR2011	NO		YES	17:00	
			04MAR2011	YES	7:00	YES	17:00	
			05MAR2011	YES	6:15	YES	17:00	
			06MAR2011	YES	7:00	YES	17:00	
			07MAR2011	YES	7:00	YES	17:00	
			08MAR2011	YES	7:00	YES	17:30	
			09MAR2011	YES	7:00			
			09MAR2011	YES	7:00	YES	17:30	
			10MAR2011	YES	6:30	YES	17:00	
			11MAR2011	YES	7:00	YES	17:00	
			12MAR2011	YES	7:00	YES	17:00	
			13MAR2011	YES	7:00	YES	17:00	
			14MAR2011	YES	6:45	YES	17:00	
			15MAR2011	YES	7:00	YES	17:00	
			16MAR2011	YES	6:45	YES	17:00	
			17MAR2011	YES	6:45	YES	17:00	
			18MAR2011	YES	7:00	YES	17:00	
			19MAR2011	YES	7:00	YES	17:45	
			20MAR2011	YES	7:00	YES	17:00	
			21MAR2011	YES	7:00	YES	17:00	
			22MAR2011	YES	6:45	YES	17:00	
			23MAR2011	YES	6:30	YES	17:45	
			24MAR2011	YES	6:30	YES	17:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	25MAR2011	YES	6:15	YES	17:00	
			26MAR2011	YES	7:00	YES	16:00	
			27MAR2011	YES	7:45	YES	17:30	
			28MAR2011	YES	7:00	YES	17:00	
			29MAR2011	YES	7:00	YES	17:15	
			30MAR2011	YES	6:15	YES	17:15	
			31MAR2011	YES	7:00	YES	17:00	
			01APR2011	YES	7:00	YES	17:45	
			02APR2011	YES	7:00	YES	17:45	
			03APR2011	YES	6:30	YES	18:00	
			04APR2011	YES	6:30	YES	17:30	
			05APR2011	YES	6:45	YES	17:30	
			06APR2011	YES	6:30	YES	17:30	
			07APR2011	YES	7:00	YES	18:00	
			08APR2011	YES	6:45	YES	17:00	
			09APR2011	YES	6:30	YES	17:30	
			10APR2011	YES	6:45	YES	17:00	
			11APR2011	YES	6:15	YES	17:00	
			12APR2011	YES	6:45	YES	17:00	
			13APR2011	YES	6:30	YES	17:00	
			14APR2011	YES	6:30	YES	17:00	
			15APR2011	YES	6:30	YES	17:00	
			16APR2011	YES	7:00	YES	17:00	
			17APR2011	YES	6:45	YES	17:00	
			18APR2011	YES	7:00	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	19APR2011	YES	6:30	YES	17:30	
			20APR2011	YES	6:45	YES	16:45	
			21APR2011	YES	6:30		18:00	
			22APR2011	YES	6:45	YES	17:00	
			23APR2011	YES	6:15	YES	18:00	
			24APR2011	YES	7:00	YES	17:00	
			25APR2011	YES	6:45	YES	17:00	
			26APR2011	YES	7:00	YES	17:00	
			27APR2011	YES	6:30	YES	17:30	
			28APR2011	YES	6:30	YES	17:45	
			29APR2011	YES	6:45	YES	17:00	
			30APR2011	YES	7:00	YES	17:30	
			01MAY2011	YES	6:00	YES	17:15	
			02MAY2011	YES	6:30	YES	17:30	
			03MAY2011	YES	6:45	YES	17:00	
			04MAY2011	YES	6:30	YES	17:00	
			05MAY2011	YES	6:30	YES	17:00	
			06MAY2011	YES	6:45	YES	17:30	
			07MAY2011	YES	6:45	YES	17:15	
			08MAY2011	YES	7:30	YES	17:00	
			09MAY2011	YES	6:30	YES	17:00	
			10MAY2011	YES	7:00	YES	17:00	
			11MAY2011	YES	6:30	YES	18:00	
			12MAY2011	YES	6:45	YES	18:00	
			13MAY2011	YES	6:45	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	14MAY2011	YES	7:00	YES	17:30	
			15MAY2011	YES	7:30	YES	17:00	
			16MAY2011	YES	6:45	YES	17:00	
			17MAY2011	YES	6:30	YES	18:30	
			18MAY2011	YES	6:45	YES	17:00	
			19MAY2011	YES	6:00			
			19MAY2011	YES	6:30	YES	18:45	
			20MAY2011	YES	6:45	YES	19:30	
			21MAY2011	YES	7:00	YES	18:15	
			22MAY2011	YES	7:00	YES	18:00	
			23MAY2011	YES	6:30	YES	17:45	
			24MAY2011	YES	6:30	YES	17:00	
			25MAY2011	YES	6:15	YES	17:00	
			26MAY2011	YES	6:30		17:45	
			27MAY2011	YES	6:30	YES	18:00	
			28MAY2011	YES	6:45	YES	17:30	
			29MAY2011	YES	7:00	YES	17:30	
			30MAY2011	YES	6:30	YES	17:30	
			31MAY2011	YES	6:30	YES	17:15	
			01JUN2011	YES	6:30	NO		
			02JUN2011	YES	7:00	YES	17:30	
			03JUN2011	YES	7:00	YES	18:00	
			04JUN2011	YES	6:30	YES	17:30	
			05JUN2011	YES	7:00	YES	17:45	
			06JUN2011	YES	6:30	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	07JUN2011	YES	6:30	YES	17:00	
			08JUN2011	YES	6:30	YES	17:30	
			09JUN2011	YES	6:15	YES	17:15	
			10JUN2011	YES	6:30	YES	18:10	
			11JUN2011	YES	7:10	YES	17:00	
			12JUN2011	YES	7:10	YES	18:00	
			13JUN2011	YES	6:30	YES	17:00	
			14JUN2011	YES	7:00	YES	17:45	
			15JUN2011	YES	6:30	YES	17:00	
			16JUN2011	YES	6:30	YES	17:10	
			17JUN2011	YES	6:30	YES	17:00	
			18JUN2011	YES	7:00	YES	17:30	
			19JUN2011	YES	7:10	YES	17:30	
			20JUN2011	YES	6:30	YES	19:00	
			21JUN2011	YES	6:30	YES	17:45	
			22JUN2011	YES	7:00	YES	17:30	
			23JUN2011	YES	7:45	YES	17:00	
			24JUN2011	YES	7:00	YES	17:00	
			25JUN2011	YES	6:45	YES	17:15	
			26JUN2011	YES	7:10	YES	17:15	
			27JUN2011	YES	6:45	YES	18:45	
			28JUN2011	YES	6:45	YES	17:00	
			29JUN2011	YES	6:45	YES	17:30	
			30JUN2011	YES	6:30	YES	19:00	
			01JUL2011	YES	6:30	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	02JUL2011	YES	6:30	YES	17:30	
			03JUL2011	YES	6:45	YES	17:00	
			04JUL2011	YES	6:30	YES	17:45	
			05JUL2011	YES	6:30	YES	17:45	
			06JUL2011	YES	7:00	YES	17:00	
			07JUL2011	YES	6:30	YES	17:30	
			08JUL2011	YES	6:45	YES	18:00	
			09JUL2011	YES	6:45	YES	17:45	
			10JUL2011	YES	7:00	YES	17:00	
			11JUL2011	YES	6:45	YES	17:15	
			12JUL2011	YES	6:30	YES	17:00	
			13JUL2011	YES	6:30	YES	17:45	
			14JUL2011	YES	6:30	YES	17:00	
			15JUL2011	YES	7:00	YES	17:00	
			16JUL2011	YES	7:30	YES	17:30	
			17JUL2011	YES	6:30	YES	17:30	
			18JUL2011	YES	6:30	YES	17:30	
			19JUL2011	YES	6:45	YES	17:15	
			20JUL2011	YES	6:30	YES	17:00	
			21JUL2011	YES	6:30	YES	19:30	
			22JUL2011	YES	6:30	YES	17:30	
			23JUL2011	YES	7:15	YES	18:30	
			24JUL2011	YES	7:15	YES	17:30	
			25JUL2011	YES	6:30	YES	17:15	
			26JUL2011	YES	7:00	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	27JUL2011	YES	7:00	YES	17:00	
			28JUL2011	YES	7:00	YES	17:45	
			29JUL2011		6:45	YES	18:00	
			30JUL2011	YES	7:15	YES	17:15	
			31JUL2011	YES	7:00	YES	18:45	
			01AUG2011	YES	6:45	YES	17:00	
			02AUG2011	YES	7:00	YES	15:30	
			03AUG2011	YES	7:00	YES	17:00	
			04AUG2011	YES	6:30	YES	19:30	
			05AUG2011	YES	7:00	YES	17:45	
			06AUG2011	YES	7:00	YES	18:30	
			07AUG2011	YES	7:00	YES	17:00	
			08AUG2011	YES	7:00	YES	19:00	
			09AUG2011	YES	6:00	YES	18:00	
			10AUG2011	YES	8:00	YES	17:00	
			11AUG2011	YES	7:30	YES	17:45	
			12AUG2011	YES	7:30	YES	18:30	
			13AUG2011	YES	7:45	YES	17:00	
			14AUG2011	YES	7:00	YES	17:30	
			15AUG2011	YES	7:30	YES	17:00	
			16AUG2011	YES	7:15	YES	18:15	
			17AUG2011	YES	7:00	YES	18:00	
			18AUG2011	YES	7:00	YES	17:45	
			19AUG2011	YES	7:00	YES	18:30	
			20AUG2011	YES	6:45	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	21AUG2011	YES	7:00	YES	17:00	
			22AUG2011	YES	6:45	YES	17:10	
			23AUG2011	YES	6:30	YES	17:15	
			24AUG2011	YES	6:15			
			24AUG2011	YES	6:30	YES	17:15	
			25AUG2011	YES	6:45	YES	17:30	
			26AUG2011	YES	6:30	YES	17:00	
			27AUG2011	YES	6:45	YES	17:30	
			28AUG2011	YES	7:15	YES	17:00	
			29AUG2011	YES	6:30	YES	17:00	
			30AUG2011	YES	6:30	YES	17:10	
			31AUG2011	YES	6:30	YES	17:30	
			01SEP2011	YES	6:30	YES	18:00	
			02SEP2011	YES	6:30	YES	15:45	
			03SEP2011	YES	7:00	YES	17:30	
			04SEP2011	YES	7:15	YES	17:00	
			05SEP2011	YES	6:30	YES	17:30	
			06SEP2011	YES	6:45	YES	17:00	
			07SEP2011	YES	6:30	YES	17:15	
			08SEP2011	YES	6:45	YES	17:30	
			09SEP2011	YES	6:45	YES	17:45	
			10SEP2011	YES	7:15	YES	17:00	
			11SEP2011	YES	6:45	YES	17:30	
			12SEP2011	YES	6:45	YES	18:00	
			13SEP2011	YES	6:30	YES	17:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	14SEP2011	YES	6:30	YES	17:15	
			15SEP2011	YES	6:30	YES	17:00	
			16SEP2011	YES	6:30	YES	17:45	
			17SEP2011	YES	7:00	YES	17:30	
			18SEP2011	YES	7:00	YES	17:00	
			19SEP2011	YES	6:30	YES	17:45	
			20SEP2011	YES	6:45	YES	17:45	
			21SEP2011	YES	6:30	YES	17:15	
			22SEP2011	YES	6:45	YES	17:15	
			23SEP2011	YES	6:45	YES	17:15	
			24SEP2011	YES	7:00	YES	18:10	
			25SEP2011	YES	7:00	YES	18:15	
			26SEP2011	YES	6:30	YES	17:30	
			27SEP2011	YES	6:30	YES	17:30	
			28SEP2011	YES	6:30	YES	17:45	
			29SEP2011	YES	6:30	YES	17:30	
			30SEP2011	YES	6:30	YES	17:10	
			01OCT2011	YES	6:30	YES	17:00	
			02OCT2011	YES	6:30	YES	17:30	
			03OCT2011	YES	6:00	YES	17:00	
			04OCT2011	YES	6:00	YES	17:15	
			05OCT2011	YES	6:45	YES	17:00	
			06OCT2011	YES	6:15	YES	17:45	
			07OCT2011	YES	6:45	YES	17:00	
			08OCT2011	YES	6:30	YES	17:15	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	09OCT2011	YES	7:00	YES	17:30	
			10OCT2011	YES	6:30	YES	17:30	
			11OCT2011	YES	6:45	YES	17:00	
			12OCT2011	YES	6:10	YES	17:00	
			13OCT2011	YES	6:45	YES	17:00	
			14OCT2011	YES	6:30	YES	17:00	
			15OCT2011	YES	5:30	YES	17:30	
			16OCT2011	YES	6:30	YES	17:00	
			17OCT2011	YES	6:30	YES	6:30	
			18OCT2011	YES	6:45	YES	17:00	
			19OCT2011	YES	6:30	YES	17:00	
			20OCT2011	YES	6:00	YES	17:45	
			21OCT2011	YES	7:30	YES	17:30	
			22OCT2011	YES	6:00	YES	19:00	
			23OCT2011	YES	6:00	YES	17:30	
			24OCT2011	YES	6:30	YES	17:30	
			25OCT2011	YES	7:30	YES	19:10	
			26OCT2011	YES	6:15	YES	17:30	
			27OCT2011	YES	6:10	YES	17:00	
			28OCT2011	YES	6:00	YES	17:15	
			29OCT2011	YES	7:30	YES	17:00	
			30OCT2011	YES	6:00	YES	17:15	
			31OCT2011	YES	6:00	YES	17:30	
			01NOV2011	YES	6:00	YES	17:00	
			02NOV2011	YES	5:00	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	03NOV2011	YES	6:30	YES	18:00	
			04NOV2011	YES	6:00	YES	17:00	
			05NOV2011	YES	6:30	YES	17:00	
			06NOV2011	YES	6:00	YES	17:00	
			07NOV2011	YES	6:00	YES	17:45	
			08NOV2011	YES	6:00	YES	17:10	
			09NOV2011	YES	6:00	YES	17:15	
			10NOV2011	YES	6:30	YES	17:00	
			11NOV2011	YES	6:00	YES	17:00	
			12NOV2011	YES	6:00	YES	17:00	
			13NOV2011	YES	7:30	YES	17:00	
			14NOV2011	YES	6:15	YES	17:00	
			15NOV2011	YES	6:00	YES	16:45	
			16NOV2011	YES	6:00	YES	17:30	
			17NOV2011	YES	6:30	YES	17:00	
			18NOV2011	YES	7:30	YES	18:00	
			19NOV2011	YES	6:00	YES	16:45	
			20NOV2011	YES	7:15	YES	17:00	
			21NOV2011	YES	6:00	YES	18:00	
			22NOV2011	YES	6:45	YES	17:10	
			23NOV2011	YES	6:30	YES	17:00	
			24NOV2011	YES	6:00	YES	17:00	
			25NOV2011	YES	6:00	YES	17:30	
			26NOV2011	YES	6:00	YES	17:00	
			27NOV2011	YES	6:00	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	069	23	28NOV2011	YES	6:00	YES	17:00	
			29NOV2011	YES	6:00	YES	16:45	
			30NOV2011	YES	6:00	YES	17:00	
			01DEC2011	YES	6:00	YES	18:00	
			02DEC2011	YES	6:30	YES	17:00	
			03DEC2011	YES	6:30	YES	17:00	
			04DEC2011	YES	7:00	YES	17:00	
			05DEC2011	YES	6:15	YES	17:00	
			06DEC2011	YES	6:00	YES	17:00	
			07DEC2011	YES	6:00	YES	17:45	
			08DEC2011	YES	6:15	YES	17:30	
			09DEC2011	YES	7:15	YES	17:30	
			10DEC2011	YES	6:00	YES	17:00	
			11DEC2011	YES	6:45	YES	17:00	
			12DEC2011	YES	6:15	YES	17:00	
			13DEC2011	YES	6:15	YES	17:00	
	072	18		YES	8:30	YES	18:30	
				YES	8:30	YES	18:30	
				YES	8:30	YES	18:30	
				YES	8:30	YES	18:30	
				YES	8:30	YES	18:30	
			22DEC2010	YES	10:00	YES	18:00	
			23DEC2010	YES	11:00	YES	17:30	
			24DEC2010	YES	10:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	25DEC2010	YES	9:58	YES	16:00	
			26DEC2010	YES	9:00	YES	17:00	
			27DEC2010	YES	10:00	YES	18:00	
			28DEC2010	YES	11:00	YES	17:00	
			29DEC2010	YES	9:30	YES	18:00	
			30DEC2010	YES	9:40	YES	19:00	
			31DEC2010	YES	8:00	YES	19:00	
			01JAN2011	YES	10:00	YES	18:00	
			02JAN2011	YES	9:00	YES	17:00	
			03JAN2011	YES		YES	17:30	
			04JAN2011	YES	8:30	YES	16:00	
			05JAN2011	YES	10:00	YES	16:45	
			06JAN2011	YES	8:45	YES	16:00	
			07JAN2011	YES	9:00	YES	17:00	
			08JAN2011	YES	9:15	YES	17:15	
			09JAN2011	YES	10:00	YES	17:00	
			10JAN2011	YES	10:15	YES	17:30	
			11JAN2011	YES	9:00	YES	16:45	
			12JAN2011	YES	9:30	YES	16:55	
			13JAN2011	YES	10:00	YES	17:00	
			14JAN2011	YES	11:00	YES	17:30	
			15JAN2011	YES	10:30	YES	17:29	
			16JAN2011	YES	10:45	YES	18:10	
			17JAN2011	YES	10:00	YES	18:10	
			18JAN2011	YES	10:00	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	19JAN2011	YES	9:30	YES	18:00	
			20JAN2011	YES	8:00			
			20JAN2011	YES	8:00	YES	17:00	Tabl. Einnahme war angebl. nach der Visite da sind sie zum Frühstück gegangen.
			21JAN2011	YES	8:10	YES	17:10	
			22JAN2011	YES	7:55	YES	16:50	
			23JAN2011	YES	8:20	YES	17:00	
			24JAN2011	YES	8:00	YES	17:10	
			25JAN2011	YES	7:30	YES	18:00	
			26JAN2011	YES	10:00	YES	17:55	
			27JAN2011	YES	9:30	YES	17:59	
			28JAN2011	YES	9:00	YES	18:15	
			29JAN2011	YES	9:30	YES	17:00	
			30JAN2011	YES	9:45	YES	17:10	
			31JAN2011	YES	9:00	YES	17:00	
			01FEB2011	YES	9:00	YES	16:55	
			02FEB2011	YES	9:10	YES	16:55	
			03FEB2011	YES	9:15	YES	17:30	
			04FEB2011	YES	9:00	YES	17:30	
			05FEB2011	YES	9:30	YES	17:45	
			06FEB2011	YES	9:30	YES	17:25	
			07FEB2011	YES	10:00	YES	18:00	
			08FEB2011	YES	10:00	YES	18:10	
			09FEB2011	YES	9:30	YES	18:05	
			10FEB2011	YES	9:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	11FEB2011	YES	9:45	YES	18:20	
			12FEB2011	YES	9:30	YES	18:00	
			13FEB2011	YES	9:15	YES	18:30	
			14FEB2011	YES	9:45	YES	18:10	
			15FEB2011	YES	9:50	YES	18:15	
			16FEB2011	YES	9:00	YES	18:00	
			17FEB2011	YES	9:00	YES	18:20	
			18FEB2011	YES	10:00	YES	18:30	
			19FEB2011	YES	9:00	YES	17:45	
			20FEB2011	YES	10:00	YES	17:50	
			21FEB2011	YES	9:30	YES	18:00	
			22FEB2011	YES	9:00	YES	18:30	
			23FEB2011	YES	10:00	YES	18:30	
			24FEB2011	YES	9:00	YES	18:30	
			25FEB2011	YES	8:30	YES	18:30	
			26FEB2011	YES	8:30	YES	18:30	
			27FEB2011	YES	8:30	YES	18:45	
			28FEB2011	YES	8:30	YES	18:30	
			01MAR2011	YES	9:00	YES	18:00	
			02MAR2011	YES	9:00	YES	18:40	
			03MAR2011	YES	9:15	YES	18:30	
			04MAR2011	YES	8:30	YES	18:30	
			05MAR2011	YES	8:45	YES	18:30	
			06MAR2011	YES	8:00	YES	18:30	
			07MAR2011	YES	8:00	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	08MAR2011	YES	8:30	YES	18:30	
			09MAR2011	YES	8:30	YES	18:30	
			10MAR2011	YES	8:30	YES	18:30	
			11MAR2011	YES	8:30	YES	18:45	
			12MAR2011	YES	8:35	YES	18:45	
			13MAR2011	YES	8:35	YES	18:40	
			14MAR2011	YES	8:35	YES	18:45	
			15MAR2011	YES	8:30			
			15MAR2011			YES	18:30	Caregiver aus der Erinnerung ausgefüllt!
			21MAR2011	YES	8:30	YES	18:30	
			22MAR2011	YES	8:30	YES	18:30	
			23MAR2011	YES	8:30	YES	18:30	
			24MAR2011	YES	8:30	YES	18:30	
			25MAR2011	YES	8:30	YES	18:30	
			26MAR2011	YES	8:30	YES	18:30	
			27MAR2011	YES	8:30	YES	18:30	
			28MAR2011	YES	8:30	YES	18:30	
			29MAR2011	YES	8:30	YES	18:30	
			30MAR2011	YES	8:30	YES	18:30	
			31MAR2011	YES	8:30	YES	18:30	
			01APR2011	YES	8:30	YES	18:30	
			02APR2011	YES	8:30	YES	18:30	
			03APR2011	YES	8:30	YES	18:30	
			04APR2011	YES	8:30	YES	18:30	
			05APR2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	06APR2011	YES	8:30	YES	18:30	
			07APR2011	YES	8:30	YES	18:30	
			08APR2011	YES	8:30	YES	18:30	
			09APR2011	YES	8:30	YES	18:30	
			10APR2011	YES	8:30	YES	18:30	
			11APR2011	YES	8:30	YES	18:30	
			12APR2011	YES	8:30	YES	18:30	
			13APR2011	YES	8:30	YES	18:30	
			14APR2011	YES	8:30	YES	18:30	
			15APR2011	YES	8:30	YES	18:30	
			16APR2011	YES	8:30	YES	18:30	
			17APR2011	YES	8:30	YES	18:30	
			18APR2011	YES	8:30	YES	18:30	
			19APR2011	YES	8:30	YES	18:30	
			20APR2011	YES	8:30	YES	18:30	
			21APR2011	YES	8:30	YES	18:30	
			22APR2011	YES	8:30	YES	18:30	
			23APR2011	YES	8:30	YES	18:30	
			24APR2011	YES	8:30	YES	18:30	
			25APR2011	YES	8:30	YES	18:30	
			26APR2011	YES	8:30	YES	18:30	
			27APR2011	YES	8:30	YES	18:30	
			28APR2011	YES	8:30	YES	18:30	
			29APR2011	YES	8:30	YES	18:30	
			30APR2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	01MAY2011	YES	8:30	YES	18:30	
			02MAY2011	YES	8:30	YES	18:30	
			03MAY2011	YES	8:30	YES	18:30	
			04MAY2011	YES	8:30	YES	18:30	
			05MAY2011	YES	8:30	YES	18:30	
			06MAY2011	YES	8:30	YES	18:30	
			07MAY2011	YES	8:30	YES	18:30	
			08MAY2011	YES	8:30	YES	18:30	
			09MAY2011	YES	8:30	YES	18:30	
			10MAY2011	YES	8:30	YES	18:30	
			11MAY2011	YES	8:30	YES	18:30	
			12MAY2011	YES	8:30	YES	18:30	
			13MAY2011	YES	8:30	YES	18:30	
			14MAY2011	YES	8:30	YES	18:30	
			15MAY2011	YES	8:30	YES	18:30	
			16MAY2011	YES	8:30	YES	18:30	
			17MAY2011	YES	8:30	YES	18:30	
			18MAY2011	YES	8:30	YES	18:30	
			19MAY2011	YES	8:30	YES	18:30	
			20MAY2011	YES	8:30	YES	18:30	
			21MAY2011	YES	8:30	YES	18:30	
			22MAY2011	YES	8:30	YES	18:30	
			23MAY2011	YES	8:30	YES	18:30	
			24MAY2011	YES	8:30	YES	18:30	
			25MAY2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	26MAY2011	YES	8:30	YES	18:30	
			27MAY2011	YES	8:30	YES	18:30	
			28MAY2011	YES	8:30	YES	18:30	
			29MAY2011	YES	8:30	YES	18:30	
			30MAY2011	YES	8:30	YES	18:30	
			31MAY2011	YES	8:30	YES	18:30	
			01JUN2011	YES	8:30	YES	18:30	
			02JUN2011	YES	8:30	YES	18:30	
			03JUN2011	YES	8:30	YES	18:30	
			04JUN2011	YES	8:30	YES	18:30	
			05JUN2011	YES	8:30	YES	18:30	
			06JUN2011	YES	8:30	YES	18:30	
			07JUN2011	YES	8:00			
			07JUN2011			YES	18:30	
			08JUN2011	YES	8:30	YES	18:30	
			09JUN2011	YES	8:30	YES	18:30	
			10JUN2011	YES	8:30	YES	18:30	
			11JUN2011	YES	8:30	YES	18:30	
			12JUN2011	YES	8:30	YES	18:30	
			13JUN2011	YES	8:30	YES	18:30	
			14JUN2011	YES	8:30	YES	18:30	
			15JUN2011	YES	8:30	YES	18:30	
			16JUN2011	YES	8:30	YES	18:30	
			17JUN2011	YES	8:30	YES	18:30	
			18JUN2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	19JUN2011	YES	8:30	YES	18:30	
			20JUN2011	YES	8:30	YES	18:30	
			21JUN2011	YES	8:30	YES	18:30	
			22JUN2011	YES	8:30	YES	18:30	
			23JUN2011	YES	8:30	YES	18:30	
			24JUN2011	YES	8:30	YES	18:30	
			25JUN2011	YES	8:30	YES	18:30	
			26JUN2011	YES	8:30	YES	18:30	
			27JUN2011	YES	8:30	YES	18:30	
			28JUN2011	YES	8:30	YES	18:30	
			29JUN2011	YES	8:30	YES	18:30	
			30JUN2011	YES	8:30	YES	18:30	
			01JUL2011	YES	8:30	YES	18:30	
			02JUL2011	YES	8:30	YES	18:30	
			03JUL2011	YES	8:30	YES	18:30	
			04JUL2011	YES	8:30	YES	18:30	
			05JUL2011	YES	8:30	YES	18:30	
			06JUL2011	YES	8:30	YES	18:30	
			07JUL2011	YES	8:30	YES	18:30	
			08JUL2011	YES	8:30	YES	18:30	
			09JUL2011	YES	8:30	YES	18:30	
			10JUL2011	YES	8:30	YES	18:30	
			11JUL2011	YES	8:30	YES	18:30	
			12JUL2011	YES	8:30	YES	18:30	
			13JUL2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	14JUL2011	YES	8:30	YES	18:30	
			15JUL2011	YES	8:30	YES	18:30	
			16JUL2011	YES	8:30	YES	18:30	
			17JUL2011	YES	8:30	YES	18:30	
			18JUL2011	YES	8:30	YES	18:30	
			19JUL2011	YES	8:30	YES	18:30	
			20JUL2011	YES	8:30	YES	18:30	
			21JUL2011	YES	8:30	YES	18:30	
			22JUL2011	YES	8:30	YES	18:30	
			23JUL2011	YES	8:30	YES	18:30	
			24JUL2011	YES	8:30	YES	18:30	
			25JUL2011	YES	8:30	YES	18:30	
			26JUL2011	YES	8:30	YES	18:30	
			27JUL2011	YES	8:30	YES	18:30	
			28JUL2011	YES	8:30	YES	18:30	
			29JUL2011	YES	8:30	YES	18:30	
			30JUL2011	YES	8:30	YES	18:30	
			31JUL2011	YES	8:30	YES	18:30	
			01AUG2011	YES	8:30	YES	18:30	
			02AUG2011	YES	8:30	YES	18:30	
			03AUG2011	YES	8:30	YES	18:30	
			04AUG2011	YES	8:30	YES	18:30	
			05AUG2011	YES	8:30	YES	18:30	
			06AUG2011	YES	8:30	YES	18:30	
			07AUG2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	08AUG2011	YES	8:30	YES	18:30	
			09AUG2011	YES	8:30	YES	18:30	
			10AUG2011	YES	8:30	YES	18:30	
			11AUG2011	YES	8:30	YES	18:30	
			12AUG2011	YES	8:30	YES	18:30	
			13AUG2011	YES	8:30	YES	18:30	
			14AUG2011	YES	8:30	YES	18:30	
			15AUG2011	YES	8:30	YES	18:30	
			16AUG2011	YES	8:30	YES	18:30	
			17AUG2011	YES	8:30	YES	18:30	
			18AUG2011	YES	8:30	YES	18:30	
			19AUG2011	YES	8:30	YES	18:30	
			20AUG2011	YES	8:30	YES	18:30	
			21AUG2011	YES	8:30	YES	18:30	
			22AUG2011	YES	8:30	YES	18:30	
			23AUG2011	YES	8:30	YES	18:30	
			24AUG2011	YES	8:30	YES	18:30	
			25AUG2011	YES	8:30	YES	18:30	
			26AUG2011	YES	8:30	YES	18:30	
			27AUG2011	YES	8:30	YES	18:30	
			28AUG2011	YES	8:30	YES	18:30	
			29AUG2011	YES	8:30	YES	18:30	
			30AUG2011	YES	7:00	YES	18:30	
			31AUG2011	YES	8:30	YES	18:30	
			01SEP2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	02SEP2011	YES	8:30	YES	18:30	
			03SEP2011	YES	8:30	YES	18:30	
			04SEP2011	YES	8:30	YES	18:30	
			05SEP2011	YES	8:30	YES	18:30	
			06SEP2011	YES	8:30	YES	18:30	
			07SEP2011	YES	8:30	YES	18:30	
			08SEP2011	YES	7:00			
			08SEP2011	YES	8:30	YES	18:30	
			09SEP2011	YES	8:30	YES	18:30	
			10SEP2011	YES	8:30	YES	18:30	
			11SEP2011	YES	8:30	YES	18:30	
			12SEP2011	YES	8:30	YES	18:30	
			13SEP2011	YES	8:30	YES	18:30	
			14SEP2011	YES	8:30	YES	18:30	
			15SEP2011	YES	8:30	YES	18:30	
			16SEP2011	YES	8:30	YES	18:30	
			17SEP2011	YES	8:30	YES	18:30	
			18SEP2011	YES	8:30	YES	18:30	
			19SEP2011	YES	8:30	YES	18:30	
			20SEP2011	YES	8:30	YES	18:30	
			21SEP2011	YES	8:30	YES	18:30	
			22SEP2011	YES	8:30	YES	18:30	
			23SEP2011	YES	8:30	YES	18:30	
			24SEP2011	YES	8:30	YES	18:30	
			25SEP2011	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	26SEP2011	YES	8:30	YES	18:30	
			27SEP2011	YES	8:30	YES	18:30	
			28SEP2011	YES	8:30	YES	18:30	
			29SEP2011	YES	8:30	YES	18:30	
			30SEP2011	YES	8:30	YES	18:30	
			01OCT2011	YES	8:30	YES	18:30	
			02OCT2011	YES	8:30	YES	18:30	
			03OCT2011	YES	8:30	YES	18:30	
			04OCT2011	YES	8:30	YES	18:30	
			05OCT2011	YES	8:30	YES	18:30	
			06OCT2011	YES	8:30	YES	18:30	
			07OCT2011	YES	8:30	YES	18:30	
			08OCT2011	YES	8:30	YES	18:30	
			09OCT2011	YES	8:30	YES	18:30	
			10OCT2011	YES	8:30	YES	18:30	
			11OCT2011	YES	8:30	YES	18:30	
			12OCT2011	YES	8:30	YES	18:30	
			13OCT2011	YES	8:30	YES	18:30	
			14OCT2011	YES	8:30	YES	18:30	
			15OCT2011	YES	8:30	YES	18:30	
			16OCT2011	YES	8:30	YES	18:30	
			17OCT2011	YES	8:30	YES	18:30	
			18OCT2011	YES	8:30	YES	18:30	
			19OCT2011	YES	8:30	YES	18:30	
			20OCT2011	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	21OCT2011	YES	8:30	YES	18:30	
			22OCT2011	YES	8:30	YES	18:30	
			23OCT2011	YES	8:30	YES	18:30	
			24OCT2011	YES	8:30	YES	18:30	
			25OCT2011	YES	8:30	YES	18:30	
			26OCT2011	YES	8:30	YES	18:30	
			27OCT2011	YES	8:30	YES	18:30	
			28OCT2011	YES	8:30	YES	18:30	
			29OCT2011	YES	8:30	YES	18:30	
			30OCT2011	YES	8:30	YES	18:30	
			31OCT2011	YES	8:30	YES	18:30	
			01NOV2011	YES	8:30	YES	18:30	
			02NOV2011	YES	8:30	YES	18:30	
			03NOV2011	YES	8:30	YES	18:30	
			04NOV2011	YES	8:30	YES	18:30	
			05NOV2011	YES	8:30	YES	18:30	
			06NOV2011	YES	8:30	YES	18:30	
			07NOV2011	YES	8:30	YES	18:30	
			08NOV2011	YES	8:30	YES	18:30	
			09NOV2011	YES	8:30	YES	18:30	
			10NOV2011	YES	8:30	YES	18:30	
			11NOV2011	YES	8:30	YES	18:30	
			12NOV2011	YES	8:30	YES	18:30	
			13NOV2011	YES	8:30	YES	18:30	
			14NOV2011	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	15NOV2011	YES	8:30	YES	18:30	
			16NOV2011	YES	8:30	YES	18:30	
			17NOV2011	YES	8:30	YES	18:30	
			18NOV2011	YES	8:30	YES	18:30	
			19NOV2011	YES	8:30	YES	18:30	
			20NOV2011	YES	8:30	YES	18:30	
			21NOV2011	YES	8:30	YES	18:30	
			22NOV2011	YES	8:30	YES	18:30	
			23NOV2011	YES	8:30	YES	18:30	
			24NOV2011	YES	8:30	YES	18:30	
			25NOV2011	YES	8:30	YES	18:30	
			26NOV2011	YES	8:30	YES	18:30	
			27NOV2011	YES	8:30	YES	18:30	
			28NOV2011	YES	8:30	YES	18:30	
			29NOV2011	YES	9:30	YES	18:30	
			30NOV2011	YES	8:30	YES	18:30	
			01DEC2011	YES	8:30	YES	18:30	
			02DEC2011	YES	8:30	YES	18:30	
			03DEC2011	YES	8:30	YES	18:30	
			04DEC2011	YES	8:30	YES	18:30	
			05DEC2011	YES	8:30	YES	18:30	
			06DEC2011	YES	8:30	YES	18:30	
			07DEC2011	YES	8:30	YES	18:30	
			08DEC2011	YES	8:30	YES	18:30	
			09DEC2011	YES	8:30	YES	18:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	072	18	10DEC2011	YES	8:30	YES	18:30	
			11DEC2011	YES	8:30	YES	18:30	
			12DEC2011	YES	8:30	YES	18:30	
			13DEC2011	YES	8:30	YES	18:30	
			14DEC2011	YES	8:30	YES	18:30	
			15DEC2011	YES	8:30			
	079	13	12AUG2010			YES	18:00	
			13AUG2010	YES	9:00	YES	18:30	
			14AUG2010	YES	9:20	YES	18:30	
			15AUG2010	YES	8:35	YES	19:00	
			16AUG2010	YES	9:10	YES	18:30	
			17AUG2010	YES	9:00	YES	18:30	
			18AUG2010	YES	9:00	YES	18:30	
			19AUG2010	YES	9:00	YES	19:05	
			20AUG2010	YES	8:30	YES	20:10	
			21AUG2010	YES	9:00	YES	18:30	
			22AUG2010	YES	9:00	YES	18:30	
			23AUG2010	YES	9:00	YES	18:00	
			24AUG2010	YES	9:00	YES	19:10	
			25AUG2010	YES	9:00	YES	18:30	
			26AUG2010	YES	9:00	YES	18:00	
			27AUG2010	YES	9:00	YES	18:00	
			28AUG2010	YES	9:30	YES	18:30	
			29AUG2010	YES	9:00	YES	21:30	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	30AUG2010	YES	8:55	YES	18:00	
			31AUG2010	YES	7:00	YES	18:00	
			01SEP2010	YES	7:50	YES	18:00	
			02SEP2010	YES	8:00	YES	18:00	
			03SEP2010	YES	8:00	YES	18:00	
			04SEP2010	YES	8:00	YES	18:00	
			05SEP2010	YES	6:30	YES	19:00	
			06SEP2010	YES	8:45	YES	18:30	
			07SEP2010	YES	8:30	YES	18:30	
			08SEP2010	YES	8:30			
			08SEP2010			YES	18:37	
			09SEP2010	YES	8:30	YES	18:30	
			10SEP2010	YES	8:15	YES	18:30	
			11SEP2010	YES	8:50	YES	19:50	
			12SEP2010	YES	8:30	YES	19:10	
			13SEP2010	YES	8:30	YES	18:30	
			14SEP2010	YES	8:30	YES	19:10	
			15SEP2010	YES	8:45	YES	19:45	
			16SEP2010	YES	9:25	YES	18:35	
			17SEP2010	YES	9:10	YES	18:40	
			18SEP2010	YES	9:00	YES	19:00	
			19SEP2010	YES	9:10	YES	18:40	
			20SEP2010	YES	9:05	YES	18:30	
			21SEP2010	YES	8:35	YES	18:25	
			22SEP2010	YES	9:25	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	23SEP2010	YES	9:00	YES	18:30	
			24SEP2010	YES	9:30	YES	18:35	
			25SEP2010	YES	9:00	YES	20:30	
			26SEP2010	YES	9:30	YES	19:00	
			27SEP2010	YES	7:10	YES	18:10	
			28SEP2010	YES	9:10	YES	19:10	
			29SEP2010	YES	8:40	YES	19:00	
			30SEP2010	YES	9:30	YES	19:30	
			01OCT2010	YES	9:30	YES	23:10	
			02OCT2010	YES	9:15	YES	19:15	
			03OCT2010	YES	9:10	YES	18:40	
			04OCT2010	YES	9:15	YES	19:00	
			05OCT2010	YES	9:00	YES	18:40	
			06OCT2010	YES	10:00	YES	19:00	
			07OCT2010	YES	8:30	YES	19:00	
			08OCT2010	YES	8:00	YES	19:00	
			09OCT2010	YES	9:10	YES	18:40	
			10OCT2010	YES	9:00	YES	18:30	
			11OCT2010	YES	9:00	YES	18:20	
			12OCT2010	YES	9:00	YES	18:30	
			13OCT2010	YES	9:15	YES	18:30	
			14OCT2010	YES	9:10	YES	18:40	
			15OCT2010	YES	9:15	YES	18:30	
			16OCT2010	YES	9:20	YES	20:10	
			17OCT2010	YES	9:10	YES	20:10	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	18OCT2010	YES	9:10	YES	19:05	
			19OCT2010	YES	8:45	YES	19:00	
			20OCT2010	YES	9:30	YES	18:45	
			21OCT2010	YES	10:00	YES	18:40	
			22OCT2010	YES	8:50	YES	18:30	
			23OCT2010	YES	7:00	YES	18:30	
			24OCT2010	YES	7:00	YES	18:30	
			25OCT2010	YES	6:00	YES	18:30	
			26OCT2010	YES	6:15	YES	18:30	
			27OCT2010	YES	6:15	YES	18:30	
			28OCT2010	YES	6:15	YES	22:20	
			29OCT2010	YES	7:40	YES	18:30	
			30OCT2010	YES	6:15	YES	18:30	
			31OCT2010	YES	5:15	YES	17:15	
			01NOV2010	YES	5:20	YES	17:15	
			02NOV2010	YES	5:15	YES	17:15	
			03NOV2010	YES	5:15	YES	21:45	
			04NOV2010	YES	5:15	YES	17:15	
			05NOV2010	YES	5:15	YES	17:30	
			06NOV2010	YES	5:15	YES	17:30	
			07NOV2010	YES	0:55	YES	18:30	07./08.11.2010
			08NOV2010	YES	8:30	YES	19:15	
			09NOV2010	YES	7:30			
			09NOV2010			YES	20:50	
			10NOV2010	YES	8:00	NO		Vergessen

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	11NOV2010	YES	8:45	YES	18:30	
			12NOV2010	YES	8:30	YES	21:40	
			13NOV2010	YES	8:45	YES	18:40	
			14NOV2010	YES	8:50	YES	19:00	
			15NOV2010	YES	8:30	YES	18:30	
			16NOV2010	YES	8:30	YES	19:15	
			17NOV2010	YES	8:45	YES	18:00	
			18NOV2010	YES	9:30	YES	19:00	
			19NOV2010	YES	9:30	YES	18:00	
			20NOV2010	YES	8:30	YES	18:50	
			21NOV2010	YES	9:30	YES	19:00	
			22NOV2010	YES	9:35	YES	18:40	
			23NOV2010	YES	9:35	YES	17:40	
			24NOV2010	YES	9:45	YES	18:45	
			25NOV2010	YES	8:45	YES	21:30	
			26NOV2010	YES	10:00	NO		vergessen
			27NOV2010	YES	10:00	YES	18:30	
			28NOV2010	YES	8:30	YES	18:30	
			29NOV2010	YES	10:00	YES	19:20	
			30NOV2010	YES	9:20	YES	19:00	
			01DEC2010	YES	10:30	YES	19:30	
			02DEC2010	YES	9:10	YES	20:00	
			03DEC2010	YES	9:10	YES	19:20	
			04DEC2010	YES	8:40	YES	20:30	
			05DEC2010	YES	10:20	YES	22:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	06DEC2010	YES	9:45	NO		vergessen
			07DEC2010	YES	9:00	YES	17:40	
			08DEC2010	YES	9:45	YES	18:30	
			09DEC2010	YES	9:00	YES	23:30	
			10DEC2010	YES	9:00	YES	18:00	
			11DEC2010	YES	9:50	YES	19:30	
			12DEC2010	YES	9:30	NO		vergessen
			13DEC2010	YES	8:50	YES	18:30	
			14DEC2010	YES	9:30	YES	18:45	
			15DEC2010	YES	10:00	YES	23:00	
			16DEC2010	YES	8:30	YES	18:30	
			17DEC2010	YES	9:45	YES	18:30	
			18DEC2010	YES	9:35	YES	18:30	
			19DEC2010	YES	9:30	YES	18:30	
			20DEC2010	YES	9:15	YES	20:30	
			21DEC2010	YES	9:15	YES	18:05	
			22DEC2010	YES	9:00	YES	18:30	
			23DEC2010	YES	9:30	YES	18:30	
			24DEC2010	YES	9:30	YES	20:00	
			25DEC2010	YES	11:00	YES	20:00	
			26DEC2010	YES	9:30	YES	20:00	
			27DEC2010	YES	8:50	YES	18:30	
			28DEC2010	YES	10:10	YES	18:30	
			29DEC2010	YES	8:45	YES	18:30	
			30DEC2010	YES	8:50	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	31DEC2010	YES	9:15	YES	19:20	
			01JAN2011	YES	9:45	NO		vergessen
			02JAN2011	YES	9:50	YES	18:10	
			03JAN2011	YES	9:15	YES	18:50	
			04JAN2011	YES	9:00	YES	18:30	
			05JAN2011	YES	9:15	YES	18:30	
			06JAN2011	YES	9:30	YES		nach 24:00 h
			07JAN2011	YES	9:30	YES	17:45	
			08JAN2011	YES	9:30	NO		vergessen
			09JAN2011	YES	9:30	NO		vergessen
			10JAN2011	YES	9:00	YES	18:30	
			11JAN2011	YES	8:30	YES	18:30	
			12JAN2011	YES	9:00	YES	18:30	
			13JAN2011	YES	8:00	YES	18:40	
			14JAN2011	YES	9:45	YES	18:30	
			15JAN2011	YES	9:30	YES	18:30	
			16JAN2011	YES	11:50	YES	23:30	
			17JAN2011	YES	9:45	YES	19:50	
			18JAN2011	YES	8:30	YES	18:30	
			19JAN2011	YES	9:30	YES	18:30	
			20JAN2011	YES	8:50	YES	22:25	
			21JAN2011	YES	9:30	YES	18:30	
			22JAN2011	YES	9:50	YES	18:30	
			23JAN2011	YES	8:40	YES	18:50	
			24JAN2011	YES	9:40	YES	18:50	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	25JAN2011	YES	9:40	YES	18:30	
			26JAN2011	YES	9:00	YES	18:30	
			27JAN2011	YES	7:30			
			27JAN2011			YES	22:10	
			28JAN2011	YES	8:30	YES	18:30	
			29JAN2011	YES	9:45	YES	20:20	
			30JAN2011	YES	8:30	YES	18:30	
			31JAN2011	YES	8:30	YES	18:30	
			01FEB2011	YES	8:30	YES	17:30	
			02FEB2011	YES	9:30	YES	20:30	
			03FEB2011	YES	8:30	YES	21:00	
			04FEB2011	YES	8:40	YES	18:30	
			05FEB2011	YES	9:10	YES	18:30	
			06FEB2011	YES	9:45	YES	18:40	
			07FEB2011	YES	7:50	YES	20:15	
			08FEB2011	YES	9:00	YES	18:25	
			09FEB2011	YES	9:05	YES	18:25	
			10FEB2011	YES	8:30	YES	17:45	
			11FEB2011	YES	8:00	YES	23:20	
			12FEB2011	YES	8:30	NO		vergessen
			13FEB2011	YES	7:30	YES	18:40	
			14FEB2011	YES	8:15	YES	22:20	
			15FEB2011	YES	8:40	YES	17:30	
			16FEB2011	YES	9:00	YES	23:30	
			17FEB2011	YES	8:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	18FEB2011	YES	7:35	YES	19:40	
			19FEB2011	YES	8:50	YES	19:40	
			20FEB2011	YES	9:40	YES	20:00	
			21FEB2011	YES	8:10	YES	20:45	
			22FEB2011	YES	8:45	YES	19:00	
			23FEB2011	YES	8:05	YES	21:30	
			24FEB2011	YES	9:00	YES	20:15	
			25FEB2011	YES	8:00	YES	21:00	
			26FEB2011	YES	8:30	YES	19:00	
			27FEB2011	YES	8:30	YES	17:45	
			28FEB2011	YES	8:30	YES	18:00	
			01MAR2011	YES	7:50	YES	18:35	
			02MAR2011	YES	8:50	YES	18:40	
			03MAR2011	YES	9:40	YES	18:00	
			04MAR2011	YES	8:00	YES	18:40	
			05MAR2011	YES	9:45	YES	19:30	
			06MAR2011	YES	9:30	YES	20:25	
			07MAR2011	YES	9:30	YES	21:00	
			08MAR2011	YES	8:20	YES	22:40	
			09MAR2011	YES	9:00	YES	17:45	
			10MAR2011	YES	9:00	YES	19:00	
			11MAR2011	YES	8:10	YES	18:30	
			12MAR2011	YES	10:00	YES	19:45	
			13MAR2011	YES	9:25	YES	22:30	
			14MAR2011	YES	8:15	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	15MAR2011	YES	8:55	YES	18:45	
			16MAR2011	YES	9:00	YES	19:10	
			17MAR2011	YES	9:00	YES	17:30	
			18MAR2011	YES	9:30	YES	23:00	
			19MAR2011	YES	9:30	YES	20:00	
			20MAR2011	YES	9:00	YES	23:50	
			21MAR2011	YES	8:20	YES	20:00	
			22MAR2011	YES	8:20	YES	20:50	
			23MAR2011	YES	9:00	YES	20:30	
			24MAR2011	YES	9:10	YES	18:00	
			25MAR2011	YES	8:10	YES	20:00	
			26MAR2011	YES	9:00	YES	19:20	
			27MAR2011	YES	9:00	YES	22:20	
			28MAR2011	YES	10:20	YES	18:30	
			29MAR2011	YES	9:30	YES	21:20	
			30MAR2011	YES	9:05	YES	22:40	
			31MAR2011	YES	8:50	YES	19:55	
			01APR2011	YES	9:00	NO		vergessen
			02APR2011	YES	11:15	YES	23:55	
			03APR2011	YES	9:45	YES	18:40	
			04APR2011	YES	9:05	YES	19:45	
			05APR2011	YES	8:30	YES	18:30	
			06APR2011	YES	8:30	YES	19:00	
			07APR2011	YES	9:30	YES	19:00	
			08APR2011	YES	9:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	09APR2011	YES	10:00	YES	19:30	
			10APR2011	YES	8:50	YES	20:40	
			11APR2011	YES	8:05			
			11APR2011			YES	19:00	
			12APR2011	YES	9:00	YES	20:05	
			13APR2011	YES	9:20	YES	18:30	
			14APR2011	YES	8:50	YES	20:25	
			15APR2011	YES	9:15	YES	18:30	
			16APR2011	YES	9:50	YES	0:45	
			17APR2011	YES	9:00	YES	18:35	
			18APR2011	YES	9:00	YES	20:30	
			19APR2011	YES	7:40	YES	18:50	
			20APR2011	YES	9:00	YES	18:30	
			21APR2011	YES	8:00	YES	17:30	
			22APR2011	YES	8:25	YES	19:30	
			23APR2011	YES	8:30	YES	18:30	
			24APR2011	YES	8:30	YES	18:30	
			25APR2011	YES	8:30	YES	18:10	
			26APR2011	YES	8:10	YES	22:30	
			27APR2011	YES	8:30	YES	20:00	
			28APR2011	YES	5:15	YES	20:40	
			29APR2011	YES	7:45	YES	18:25	
			30APR2011	YES	7:15	YES	20:30	
			01MAY2011	YES	8:30	YES	23:50	
			02MAY2011	YES	9:45	YES	18:45	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	03MAY2011	YES	10:00	YES	19:00	
			04MAY2011	YES	9:10	YES	20:10	
			05MAY2011	YES	7:45	YES	18:30	
			06MAY2011	YES	9:10	YES	20:00	
			07MAY2011	YES	9:15	YES	21:45	
			08MAY2011	YES	9:00	YES	19:00	
			09MAY2011		9:10	YES	20:30	
			10MAY2011	YES	8:45	YES	18:55	
			11MAY2011	YES	9:45	YES	19:00	
			12MAY2011	YES	10:25	YES	18:00	
			13MAY2011	YES	9:15	YES	18:30	
			14MAY2011	YES	8:10	YES	17:30	
			15MAY2011	YES	8:20	YES	18:20	
			16MAY2011	YES	8:30	YES	18:00	
			17MAY2011	YES	8:30	YES	21:45	
			18MAY2011	YES	6:10	YES	18:15	
			19MAY2011	YES	8:15	YES	18:10	
			20MAY2011	YES	8:30	YES	18:00	
			21MAY2011	YES	8:30	YES	18:00	
			22MAY2011	YES	8:05	YES	21:15	
			23MAY2011	YES	7:30	YES	18:15	
			24MAY2011	YES	8:35	YES	18:20	
			25MAY2011	YES	8:45	YES	18:15	
			26MAY2011	YES	6:00	YES	23:20	
			27MAY2011	YES	8:45	YES	18:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	079	13	28MAY2011	YES	9:45	YES	20:55	
			29MAY2011	YES	8:45	YES	18:40	
			30MAY2011	YES	8:30	YES	18:00	
			31MAY2011	YES	10:00	YES	18:30	
			01JUN2011	YES	9:15	YES	20:00	
			02JUN2011	YES	9:00	YES	19:45	
			03JUN2011	YES	8:00	YES	18:15	
			04JUN2011	NO		NO		2x vergessen
			05JUN2011	YES	9:55	YES	22:10	
			06JUN2011	YES	9:25	YES	19:20	
			07JUN2011	YES	10:15	YES	18:10	
			08JUN2011	YES	10:00	YES	21:00	
			09JUN2011	YES	9:40	YES	18:30	
			10JUN2011	YES	8:15	YES	0:35	
			11JUN2011	YES	9:30	YES	19:40	
			12JUN2011	YES	8:20	YES	18:30	
			13JUN2011	YES	9:45	NO		vergessen
			14JUN2011	YES	8:45	YES	18:55	
			15JUN2011	YES	9:10	YES	17:40	
			16JUN2011	YES	9:00	YES	18:30	
			17JUN2011	YES	9:00	YES	0:30	
			18JUN2011	YES	9:00	YES	19:00	
			19JUN2011	YES	9:00	YES	18:40	
			20JUN2011	YES	10:15	YES	19:00	
			21JUN2011	YES	8:10			

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	14OCT2010			YES	18:25	
			15OCT2010	YES	8:00	YES	18:30	
			16OCT2010	YES	8:10	YES	18:15	
			17OCT2010	YES	8:10	YES	18:30	
			18OCT2010	YES	8:00	YES	18:30	
			19OCT2010	YES	8:00	YES	18:30	
			20OCT2010	YES	8:00	YES	18:30	
			21OCT2010	YES	8:00	YES	18:30	
			22OCT2010	YES	8:10	YES	18:45	
			23OCT2010	YES	8:15	YES	18:45	
			24OCT2010	YES	8:15	YES	18:30	
			25OCT2010	YES	8:00	YES	18:30	
			26OCT2010	YES	8:15	YES	18:45	
			27OCT2010	YES	8:11	YES	18:55	
			28OCT2010	YES	8:30	YES	18:30	
			29OCT2010	YES	8:00	YES	18:00	
			30OCT2010	YES	8:00	YES	18:15	
			31OCT2010	YES	8:00	YES	18:15	
			01NOV2010	YES	8:00	YES	18:30	
			02NOV2010	YES	8:00	YES	18:30	
			03NOV2010	YES	8:00	YES	18:30	
			04NOV2010	YES	8:00	YES	18:30	
			05NOV2010	YES	8:00	YES	18:30	
			06NOV2010	YES	8:10	YES	18:45	
			07NOV2010		8:15	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	08NOV2010	YES	8:10	YES	18:50	
			09NOV2010	YES	8:15	YES	18:25	
			10NOV2010	YES	8:10	YES	18:30	
			11NOV2010	YES	8:10	YES	18:30	
			12NOV2010	YES	8:00	YES	18:30	
			13NOV2010	YES	8:00	YES	18:45	
			14NOV2010	YES	8:20	YES	19:00	
			15NOV2010	YES	8:20	YES	19:10	
			16NOV2010	YES	8:20	YES	19:00	
			17NOV2010			YES	19:00	
			18NOV2010	YES	8:00	YES	19:00	
			19NOV2010	YES	8:00	YES	19:00	
			20NOV2010	YES	8:30	YES	19:10	
			21NOV2010	YES	8:30	YES	19:20	
			22NOV2010	YES	8:30	YES	19:25	
			23NOV2010	YES	8:30	YES	19:20	
			24NOV2010	YES	8:15	YES	19:20	
			25NOV2010	YES	8:13	YES	19:11	
			26NOV2010	YES	8:00	YES	19:15	
			27NOV2010	YES	8:30	YES	19:15	
			28NOV2010	YES	8:30	YES	19:15	
			29NOV2010	YES	7:15	YES	19:15	
			30NOV2010	YES	8:00	YES	19:00	
			01DEC2010	YES	7:50	YES	18:30	
			02DEC2010	YES	7:30	YES	18:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	03DEC2010	YES	7:15	YES	18:00	
			04DEC2010	YES	7:25	YES	18:01	
			05DEC2010	YES	8:00	YES	19:00	
			06DEC2010	YES	8:30	YES	19:00	
			07DEC2010	YES	8:00	YES	19:00	
			08DEC2010	YES	8:30	YES	19:10	
			09DEC2010	YES	8:30	YES	19:10	
			10DEC2010	YES	8:15	YES	18:15	
			11DEC2010	YES	8:15	YES	18:15	
			12DEC2010	YES	8:15	YES	18:15	
			13DEC2010	YES	8:15	YES	18:30	
			14DEC2010	YES	7:30	YES	18:30	
			15DEC2010	YES	7:30	YES	18:30	
			16DEC2010	YES	7:30	YES	18:30	
			17DEC2010	YES	7:45	YES	18:15	
			18DEC2010	YES	7:45	YES	19:00	
			19DEC2010	YES	7:45	YES	19:00	
			20DEC2010	YES	7:45	YES	19:00	
			21DEC2010	YES	7:45	YES	19:00	
			22DEC2010	YES	8:00	YES	19:00	
			23DEC2010	YES	8:00	YES	20:00	
			24DEC2010	YES	8:00	YES	20:00	
			25DEC2010	YES	9:00	YES	20:00	
			26DEC2010	YES	9:00	YES	21:00	
			27DEC2010	YES	9:00	YES	21:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	28DEC2010	YES	8:00	YES	18:00	
			29DEC2010	YES	8:00	YES	18:00	
			30DEC2010	YES	8:00	YES	18:00	
			31DEC2010	YES	9:00	YES	20:00	
			01JAN2011	YES	8:00	YES	20:00	
			02JAN2011	YES	8:00	YES	20:00	
			03JAN2011	YES	8:15	YES	20:30	
			04JAN2011	YES	8:15	YES	20:30	
			05JAN2011	YES	7:30			
			05JAN2011			YES	20:00	
			06JAN2011	YES	8:00	YES	20:00	
			07JAN2011	YES	8:00	YES	20:00	
			08JAN2011	YES	8:10	YES	20:00	
			09JAN2011	YES	8:10	YES	20:00	
			10JAN2011	YES	8:15	YES	20:00	
			11JAN2011	YES	8:15	YES	20:00	
			12JAN2011	YES	8:15	YES	20:00	
			13JAN2011	YES	8:00	YES	20:00	
			14JAN2011	YES	8:00	YES	20:00	
			15JAN2011	YES	8:10	YES	20:00	
			16JAN2011	YES	8:10	YES	20:01	
			17JAN2011	YES	8:15	YES	20:00	
			18JAN2011	YES	7:45	YES	20:00	
			19JAN2011	YES	7:45	YES	18:00	
			20JAN2011	YES	7:45	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	21JAN2011	YES	7:45	YES	18:00	
			22JAN2011	YES	8:10	YES	19:00	
			23JAN2011	YES	8:10	YES	20:00	
			24JAN2011	YES	8:10	YES	19:30	
			25JAN2011	YES	8:10	YES	20:00	
			26JAN2011	YES	8:10	YES	20:45	
			27JAN2011	YES	8:15	YES	20:45	
			28JAN2011	YES	8:20	YES	20:45	
			29JAN2011	YES	8:15	YES	20:00	
			30JAN2011	YES	8:20	YES	20:00	
			31JAN2011	YES	7:30	YES	18:00	
			01FEB2011	YES	7:30	YES	18:00	
			02FEB2011	YES	7:30	YES	18:00	
			03FEB2011	YES	7:30	YES	18:00	
			04FEB2011	YES	7:30	YES	18:00	
			05FEB2011	YES	7:30	YES	19:00	
			06FEB2011	YES	7:30	YES	19:00	
			07FEB2011	YES	7:45	YES	19:00	
			08FEB2011	YES	7:45	YES	19:00	
			09FEB2011	YES	8:00	YES	19:00	08:00 + 19:00 immer die selbe Zeit
			10FEB2011	YES	8:00	YES	19:00	
			11FEB2011	YES	8:00	YES	19:00	
			12FEB2011	YES	8:00	YES	19:00	
			13FEB2011	YES	8:00	YES	19:00	
			14FEB2011	YES	8:00	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	15FEB2011	YES	8:00	YES	19:00	
			16FEB2011	YES	8:00	YES	19:00	
			17FEB2011	YES	8:00	YES	19:00	
			18FEB2011	YES	8:00	YES	19:00	
			19FEB2011	YES	8:00	YES	19:00	
			20FEB2011	YES	8:00	YES	19:00	
			21FEB2011	YES	8:00	YES	19:00	
			22FEB2011	YES	8:00	YES	19:00	
			23FEB2011	YES	8:00	YES	19:00	
			24FEB2011	YES	8:00	YES	19:00	
			25FEB2011	YES	8:00	YES	19:00	
			26FEB2011	YES	8:00	YES	19:00	
			27FEB2011	YES	8:00	YES	20:00	08:00 + 20:00
			28FEB2011	YES	8:00	YES	20:00	
			01MAR2011	YES	8:00	YES	20:00	
			02MAR2011	YES	8:00	YES	20:00	
			03MAR2011	YES	8:00	YES	20:00	
			04MAR2011	YES	8:00	YES	20:00	
			05MAR2011	YES	8:00	YES	20:00	
			06MAR2011	YES	8:00	YES	20:00	
			07MAR2011	YES	8:00	YES	20:00	
			08MAR2011	YES	8:15	YES	20:00	
			09MAR2011	YES	8:15	YES	20:00	
			10MAR2011	YES	8:15	YES	20:00	
			11MAR2011	YES	8:15	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	12MAR2011	YES	8:15	YES	20:50	
			13MAR2011	YES	8:15	YES	20:50	
			14MAR2011	YES	18:10	YES	20:50	
			15MAR2011	YES	18:10	YES	20:50	
			16MAR2011	YES	18:10	YES	20:45	
			17MAR2011	YES	8:00	YES	19:30	Die beste Zeit ist 08:00 + 19:30
			18MAR2011	YES	8:00	YES	19:30	
			19MAR2011	YES	8:00	YES	19:30	
			20MAR2011	YES	8:00	YES	19:30	
			21MAR2011	YES	8:00	YES	19:30	
			22MAR2011	YES	8:00	YES	19:30	
			23MAR2011	YES	8:00	YES	19:30	
			24MAR2011	YES	8:00	YES	19:30	
			25MAR2011	YES	8:00	YES	19:30	
			26MAR2011	YES	8:00	YES	20:00	
			27MAR2011	YES	8:00	YES	20:00	
			28MAR2011	YES	8:00	YES	20:00	
			29MAR2011	YES	8:00	YES	20:00	
			30MAR2011	YES	8:00	YES	20:00	
			31MAR2011	YES	8:00	YES	20:00	
			01APR2011	YES	8:00	YES	20:00	
			02APR2011	YES	8:00	YES	20:00	
			03APR2011	YES	8:00	YES	20:00	
			05APR2011	YES	8:00	YES	20:00	
			06APR2011	YES	7:30			

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	06APR2011			YES	19:00	
			07APR2011	YES	7:30	YES	20:00	
			08APR2011	YES	7:30	YES	20:00	
			09APR2011	YES	7:30	YES	20:00	
			10APR2011	YES	7:30	YES	20:00	
			11APR2011	YES	7:30	YES	20:00	
			12APR2011	YES	7:30	YES	20:00	
			13APR2011	YES	7:30	YES	20:00	
			14APR2011	YES	7:30	YES	20:00	
			15APR2011	YES	7:45	YES	20:15	
			16APR2011	YES	7:45	YES	20:00	
			17APR2011	YES	7:30	YES	20:00	
			18APR2011	YES	7:15	YES	20:05	
			19APR2011	YES	7:15	YES	20:05	
			20APR2011	YES	7:30	YES	20:05	
			21APR2011	YES	7:50	YES	20:15	
			22APR2011	YES	7:55	YES	20:15	
			23APR2011	YES	7:55	YES	19:50	
			24APR2011	YES	7:30	YES	20:00	
			25APR2011	YES	7:30	YES	20:00	
			26APR2011	YES	7:30	YES	20:00	
			27APR2011	YES	7:30	YES	20:00	
			28APR2011	YES	7:30	YES	20:00	
			29APR2011	YES	7:30	YES	20:00	
			30APR2011	YES	7:30	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	01MAY2011	YES	7:30	YES	20:00	
			02MAY2011	YES	7:30	YES	20:00	
			03MAY2011	YES	7:30	YES	20:05	
			04MAY2011	YES	7:50	YES	20:05	
			05MAY2011	YES	7:50	YES	20:00	
			06MAY2011	YES	7:50	YES	20:00	
			07MAY2011	YES	7:50	YES	20:00	
			08MAY2011	YES	7:50	YES	20:00	
			09MAY2011	YES	7:50	YES	20:00	
			10MAY2011	YES	7:50	YES	20:00	
			11MAY2011	YES	7:50	YES	20:00	
			12MAY2011	YES	7:30	YES	20:00	
			13MAY2011	YES	7:30	YES	20:15	
			14MAY2011	YES	7:30	YES	20:15	
			15MAY2011	YES	7:30	YES	20:15	
			16MAY2011	YES	7:30	YES	20:15	
			17MAY2011	YES	7:30	YES	20:15	
			18MAY2011	YES	7:30	YES	19:45	
			19MAY2011	YES	7:30	YES	19:45	
			20MAY2011	YES	7:30	YES	19:45	
			21MAY2011	YES	7:15	YES	19:30	
			22MAY2011	YES	7:15	YES	19:45	
			23MAY2011	YES	7:20	YES	19:45	
			24MAY2011	YES	7:20	YES	19:45	
			25MAY2011	YES	7:30	YES	19:50	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	26MAY2011	YES	7:20	YES	19:50	
			27MAY2011	YES	7:15	YES	19:50	
			28MAY2011	YES	7:15	YES	19:50	
			29MAY2011	YES	7:20	YES	19:50	
			30MAY2011	YES	7:30	YES	20:00	
			31MAY2011	YES	7:30	YES	20:00	
			01JUN2011	YES	7:30	YES	19:30	
			02JUN2011	YES	7:30	YES	19:30	
			03JUN2011	YES	7:35	YES	19:45	
			04JUN2011	YES	7:35	YES	19:45	
			05JUN2011	YES	7:40	YES	19:45	
			06JUN2011	YES	7:15	YES	19:50	
			07JUN2011	YES	7:15	YES	19:50	
			08JUN2011	YES	8:30	YES	19:30	
			09JUN2011	YES	8:45	YES	19:30	
			10JUN2011	YES	8:15	YES	19:35	
			11JUN2011	YES	8:15	YES	19:35	
			12JUN2011	YES	8:15	YES	19:35	
			13JUN2011	YES	8:20	YES	19:40	
			14JUN2011	YES	8:20	YES	19:40	
			15JUN2011	YES	8:30	YES	19:30	
			16JUN2011	YES	8:30	YES	19:30	
			17JUN2011	YES	7:15	YES	20:00	
			18JUN2011	YES	7:20	YES	20:00	
			19JUN2011	YES	7:30	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	20JUN2011	YES	7:15	YES	19:30	
			21JUN2011	YES	7:15	YES	19:30	
			22JUN2011	YES	7:15			
			22JUN2011			YES	19:40	
			23JUN2011	YES	8:00	YES	19:00	
			24JUN2011	YES	8:00	YES	19:00	
			25JUN2011	YES	8:00	YES	19:00	
			26JUN2011	YES	8:00	YES	19:00	
			27JUN2011	YES	8:10	YES	19:00	
			28JUN2011	YES	8:10	YES	19:00	
			29JUN2011	YES	8:00	YES	19:00	
			30JUN2011	YES	8:00	YES	19:00	
			01JUL2011	YES	8:00	YES	19:00	
			02JUL2011	YES	8:00	YES	19:00	
			03JUL2011	YES	8:00	YES	19:00	
			04JUL2011	YES	8:10	YES	19:00	
			05JUL2011	YES	8:10	YES	19:30	
			06JUL2011	YES	8:10	YES	19:15	
			07JUL2011	YES	8:10	YES	19:15	
			08JUL2011	YES	8:10	YES	19:15	
			09JUL2011	YES	8:10	YES	19:15	
			10JUL2011	YES	8:00	YES	19:00	
			11JUL2011	YES	8:00	YES	19:00	
			12JUL2011	YES	8:15	YES	19:00	
			13JUL2011	YES	8:10	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	14JUL2011	YES	8:10	YES	19:15	
			15JUL2011	YES	8:10	YES	19:15	
			16JUL2011	YES	8:10	YES	19:15	
			17JUL2011	YES	8:00	YES	19:00	
			18JUL2011	YES	8:00	YES	19:00	
			19JUL2011	YES	8:00	YES	19:00	
			20JUL2011	YES	8:00	YES	19:00	
			21JUL2011	YES	8:00	YES	19:00	
			22JUL2011	YES	8:10	YES	19:00	
			23JUL2011	YES	8:10	YES	19:00	
			24JUL2011	YES	8:00	YES	19:00	
			25JUL2011	YES	8:00	YES	19:10	
			26JUL2011	YES	8:10	YES	19:00	
			27JUL2011	YES	8:00	YES	19:00	
			28JUL2011	YES	8:00	YES	19:10	
			29JUL2011	YES	8:05	YES	19:10	
			30JUL2011	YES	8:10	YES	19:10	
			31JUL2011	YES	8:00	YES	19:00	
			01AUG2011	YES	8:00	YES	19:00	
			02AUG2011	YES	8:00	YES	19:00	
			03AUG2011	YES	8:00	YES	19:00	
			04AUG2011	YES	8:00	YES	19:00	Nicht genau
			05AUG2011	YES	8:00	YES	19:00	
			06AUG2011	YES	8:00	YES	19:00	
			07AUG2011	YES	8:10	YES	19:10	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	08AUG2011	YES	8:10	YES	19:10	Nicht genau
			09AUG2011	YES	8:10	YES	19:20	
			10AUG2011	YES	8:40	YES	19:20	
			11AUG2011	YES	8:10	YES	19:10	Nicht genau
			12AUG2011	YES	8:20	YES	19:20	
			13AUG2011	YES	8:30	YES	19:10	
			14AUG2011	YES	8:10	YES	19:10	
			15AUG2011	YES	8:10	YES	19:00	Nicht genau
			16AUG2011	YES	8:00	YES	19:00	
			17AUG2011	YES	8:00	YES	19:00	
			18AUG2011	YES	8:00	YES	19:30	Nicht genau
			19AUG2011	YES	8:10	YES	19:30	
			20AUG2011	YES	8:20	YES	19:30	
			21AUG2011	YES	8:20	YES	19:30	
			22AUG2011	YES	8:30	YES	19:10	
			23AUG2011	YES	8:40	YES	19:00	
			24AUG2011	YES	8:00	YES	19:00	
			25AUG2011	YES	8:00	YES	19:00	Nicht genau
			26AUG2011	YES	8:00	YES	19:10	
			27AUG2011	YES	8:10	YES	19:15	
			28AUG2011	YES	8:15	YES	19:30	
			29AUG2011	YES	8:30	YES	19:30	Nicht genau
			30AUG2011	YES	8:10	YES	19:30	
			31AUG2011	YES	8:15	YES	19:00	
			01SEP2011	YES	8:10	YES	19:10	Nicht genau

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	02SEP2011	YES	8:00	YES	19:00	
			03SEP2011	YES	8:00	YES	19:00	
			04SEP2011	YES	8:00	YES	19:15	
			05SEP2011	YES	8:00	YES	19:15	Nicht genau
			06SEP2011	YES	8:00	YES	19:20	
			07SEP2011	YES	8:00	YES	19:15	
			08SEP2011	YES	8:10	YES	19:15	Nicht genau
			09SEP2011	YES	8:00	YES	19:30	
			10SEP2011	YES	8:10	YES	19:30	
			11SEP2011	YES	8:00	YES	19:00	
			12SEP2011	YES	8:00	YES	19:00	Nicht genau
			13SEP2011	YES	8:30	YES	19:15	
			14SEP2011	YES	8:30	YES	19:30	
			15SEP2011	YES	8:15	YES	19:30	Nicht genau
			16SEP2011	YES	8:15	YES	19:30	
			17SEP2011	YES	8:15	YES	19:30	
			18SEP2011	YES	8:15	YES	19:30	
			19SEP2011	YES	8:15	YES	19:30	Nicht genau
			20SEP2011	YES	8:00	YES	19:30	
			21SEP2011	YES	8:00	YES	19:30	
			22SEP2011	YES	8:10	YES	19:30	Nicht genau
			23SEP2011	YES	8:10	YES	19:30	
			24SEP2011	YES	8:10	YES	19:30	
			25SEP2011	YES	8:15	YES	19:30	
			26SEP2011	YES	8:15	YES	19:30	Nicht genau

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	082	17	27SEP2011	YES	8:15	YES	19:30	
			28SEP2011	YES	8:15	YES	19:30	
			29SEP2011	YES	8:10	YES	19:30	Nicht genau
			30SEP2011	YES	8:10	YES	19:30	
			01OCT2011	YES	8:15	YES	19:30	
			02OCT2011	YES	8:15	YES	19:30	
			03OCT2011	YES	9:00	YES	19:10	Nicht genau
			04OCT2011	YES	8:15	YES	19:10	
			05OCT2011	YES	8:10	YES	19:15	
			06OCT2011	YES	8:15	YES	19:15	
			07OCT2011	YES	8:15	YES	19:15	
			08OCT2011	YES	8:10	YES	19:30	
			09OCT2011	YES	8:00	YES	19:00	
			10OCT2011	YES	8:15	YES	19:45	Nicht genau
			11OCT2011	YES	8:15	YES	19:30	
			12OCT2011	YES	7:30			
	084	17	17NOV2010			YES	19:00	
			18NOV2010	YES	8:30	YES	18:00	
			19NOV2010	YES	8:30	YES	18:00	
			20NOV2010	YES	8:15	YES	18:00	
			21NOV2010	YES	8:15	YES	18:05	
			22NOV2010	YES	8:15	YES	18:05	
			23NOV2010	YES	7:45	YES	19:30	
			24NOV2010	YES	7:40	YES	19:25	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	25NOV2010	YES	7:35	YES	19:30	
			26NOV2010	YES	7:28	YES	20:30	
			27NOV2010	YES	7:30	YES	18:20	
			28NOV2010	YES	7:20	YES	19:10	
			29NOV2010	YES	8:00	YES	20:05	
			30NOV2010	YES	8:30	YES	20:01	
			01DEC2010	YES	8:15	YES	20:05	
			02DEC2010	YES	7:50	YES	18:49	
			03DEC2010	YES	7:50	YES	18:30	
			04DEC2010	YES	7:50	YES	18:30	
			05DEC2010	YES	7:30	YES	18:10	
			06DEC2010	YES	7:30	YES	18:10	
			07DEC2010	YES	7:30	YES	18:00	
			08DEC2010	YES	7:40	YES	18:00	
			09DEC2010	YES	7:30	YES	18:00	
			10DEC2010	YES	8:15	YES	20:00	
			11DEC2010	YES	8:15	YES	19:45	
			12DEC2010	YES	8:15	YES	19:30	
			13DEC2010	YES	8:15	YES	19:30	
			14DEC2010	YES	8:00	YES	19:00	
			15DEC2010		7:30			
			15DEC2010			YES	20:00	
			16DEC2010	YES	8:00	YES	20:00	
			17DEC2010	YES	8:00	YES	19:30	
			18DEC2010	YES	8:00	YES	19:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	19DEC2010	YES	8:00	YES	19:30	
			20DEC2010	YES	8:10	YES	19:30	
			21DEC2010	YES	8:10	YES	19:45	
			22DEC2010	YES	8:00	YES	19:30	
			23DEC2010	YES	8:00	YES	20:00	
			24DEC2010	YES	8:10	YES	20:00	
			25DEC2010	YES	7:40	YES	20:10	
			26DEC2010	YES	8:00	YES	20:50	
			27DEC2010	YES	8:00	YES	20:00	
			28DEC2010	YES	7:50	YES	19:30	
			29DEC2010	YES	7:30	YES	19:30	
			30DEC2010	YES	7:30	YES	19:30	
			31DEC2010	YES	8:30	YES	21:00	
			01JAN2011	YES	9:00	YES	20:00	
			02JAN2011	YES	9:00	YES	20:00	
			03JAN2011	YES	9:00	YES	20:00	
			04JAN2011	YES	8:30	YES	19:30	
			05JAN2011	YES	8:30	YES	19:30	
			06JAN2011	YES	7:30	YES	19:00	
			07JAN2011	YES	8:00	YES	19:00	
			08JAN2011	YES	8:00	YES	19:00	
			09JAN2011	YES	8:00	YES	19:00	
			10JAN2011	YES	7:50	YES	19:30	
			11JAN2011	YES	7:50	YES	19:30	
			12JAN2011	YES	7:30	YES	19:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	13JAN2011	YES	7:45	YES	19:38	
			14JAN2011	YES	7:50	YES	19:30	
			15JAN2011	YES	7:51	YES	19:48	
			16JAN2011	YES	7:50	YES	19:10	
			17JAN2011	YES	7:18	YES	19:20	
			18JAN2011	YES	7:36	YES	20:00	
			19JAN2011	YES	8:15	YES	19:00	
			20JAN2011	YES	8:15	YES	19:00	
			21JAN2011	YES	8:15	YES	19:00	
			22JAN2011	YES	8:15	YES	19:30	
			23JAN2011	YES	8:15	YES	19:20	
			24JAN2011	YES	8:15	YES	19:30	
			25JAN2011	YES	8:15	YES	19:15	
			26JAN2011	YES	8:15	YES	19:30	
			27JAN2011	YES	8:15	YES	19:10	
			28JAN2011	YES	8:30	YES	19:00	
			29JAN2011	YES	8:25	YES	19:00	
			30JAN2011	YES	7:50	YES	19:00	
			31JAN2011	YES	8:00	YES	20:00	
			01FEB2011	YES	8:00	YES	20:00	
			02FEB2011	YES	8:00	YES	20:00	
			03FEB2011	YES	7:30	YES	20:00	
			04FEB2011	YES	7:30	YES	20:00	
			05FEB2011	YES	7:30	YES	20:00	
			06FEB2011	YES	8:00	YES	18:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	07FEB2011	YES	8:00	YES	19:00	
			08FEB2011	YES	8:00			
			09FEB2011			YES	19:00	
			10FEB2011	YES	8:00	YES	18:00	
			11FEB2011	YES	8:00	YES	18:00	
			12FEB2011	YES	8:00	YES	18:00	
			13FEB2011	YES	8:00	YES	19:00	
			14FEB2011	YES	8:00	YES	19:00	
			15FEB2011	YES	8:00	YES	19:00	
			16FEB2011	YES	8:00	YES	19:00	
			17FEB2011	YES	8:00	YES	19:00	
			18FEB2011	YES	7:30	YES	19:00	
			19FEB2011	YES	7:30	YES	20:00	
			20FEB2011	YES	7:30	YES	20:00	
			21FEB2011	YES	7:30	YES	20:00	
			22FEB2011	YES	7:30	YES	20:00	
			23FEB2011	YES	7:30	YES	20:00	
			24FEB2011	YES	7:30	YES	20:00	
			25FEB2011	YES	7:30	YES	20:00	
			26FEB2011	YES	7:20	YES	20:00	
			27FEB2011	YES	8:00	YES	19:30	
			28FEB2011	YES	8:00	YES	19:30	
			01MAR2011	YES	8:00	YES	19:30	
			02MAR2011	YES	8:00	YES	19:30	
			03MAR2011	YES	8:00	YES	19:30	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	04MAR2011	YES	8:10	YES	19:20	
			05MAR2011	YES	8:10	YES	19:20	
			06MAR2011	YES	8:15	YES	19:30	
			07MAR2011	YES	8:00	YES	19:30	
			08MAR2011	YES	8:05	YES	19:30	
			09MAR2011	YES	8:05	YES	19:30	
			10MAR2011	YES	8:05	YES	19:30	
			11MAR2011	YES	8:05	YES	19:30	
			12MAR2011	YES	8:01	YES	19:20	
			13MAR2011	YES	8:00	YES	19:00	
			14MAR2011	YES	8:00	YES	20:00	
			15MAR2011	YES	8:00	YES	20:00	
			16MAR2011	YES	8:00	YES	19:00	
			17MAR2011	YES	8:10	YES	19:30	
			18MAR2011	YES	8:10	YES	19:30	
			19MAR2011	YES	8:10	YES	19:30	
			20MAR2011	YES	8:00	YES	19:00	
			21MAR2011	YES	8:10	YES	19:00	
			22MAR2011	YES	8:05	YES	19:00	
			23MAR2011	YES	8:05	YES	19:05	
			24MAR2011	YES	8:05	YES	19:05	
			25MAR2011	YES	7:20	YES	19:00	
			26MAR2011	YES	7:30	YES	19:00	
			27MAR2011	YES	7:50	YES	19:00	
			28MAR2011	YES	8:10	YES	19:05	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	29MAR2011	YES	8:10	YES	19:05	
			30MAR2011	YES	8:15	YES	19:10	
			31MAR2011	YES	8:15	YES	19:20	
			01APR2011	YES	8:30	YES	19:20	
			02APR2011	YES	8:45	YES	19:00	
			03APR2011	YES	8:00	YES	19:00	
			04APR2011	YES	8:00	YES	19:00	
			05APR2011	YES	8:10	YES	19:10	
			06APR2011	YES	8:10	YES	19:10	
			07APR2011	YES	8:15	YES	20:00	
			08APR2011	YES	8:15	YES	19:10	
			09APR2011	YES	8:15	YES	19:10	
			10APR2011	YES	8:10	YES	20:10	
			11APR2011	YES	8:10	YES	20:00	
			12APR2011	YES	7:30	YES	19:00	
			13APR2011	YES	7:30	YES	19:00	
			14APR2011	YES	7:30	YES	19:30	
			15APR2011	YES	7:45	YES	19:30	
			16APR2011	YES	7:45	YES	19:31	
			17APR2011	YES	7:20	YES	19:31	
			18APR2011	YES	7:20	YES	19:30	
			19APR2011	YES	7:30	YES	19:00	
			20APR2011	YES	7:30	YES	19:00	
			21APR2011	YES	7:15	YES	19:00	
			22APR2011	YES	7:15	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	23APR2011	YES	7:20	YES	19:00	
			24APR2011	YES	7:30	YES	20:00	
			25APR2011	YES	7:30	YES	21:00	
			26APR2011	YES	7:30	YES	21:00	
			27APR2011	YES	7:45	YES	19:30	
			28APR2011	YES	7:45	YES	19:30	
			29APR2011	YES	7:45	YES	19:30	
			30APR2011	YES	7:30	YES	19:00	
			01MAY2011	YES	7:30	YES	19:00	
			02MAY2011	YES	7:30	YES	19:00	
			03MAY2011	YES	8:30	YES	20:10	
			04MAY2011	YES	7:45			
			05MAY2011	YES	7:45			
			09MAY2011	YES	7:30	YES	20:00	
			10MAY2011	YES	7:45			
			10MAY2011			YES	20:00	
			11MAY2011	YES	7:50	YES	20:00	
			12MAY2011	YES	7:50	YES	19:30	
			13MAY2011	YES	8:00	YES	19:30	
			14MAY2011	YES	8:00	YES	19:30	
			15MAY2011	YES	8:00	YES	19:45	
			16MAY2011	YES	8:15	YES	19:45	
			17MAY2011	YES	8:15	YES	19:45	
			18MAY2011	YES	8:15	YES	19:45	
			19MAY2011	YES	7:45	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	20MAY2011	YES	7:55	YES	20:00	
			21MAY2011	YES	7:30	YES	20:00	
			22MAY2011	YES	7:30	YES	19:30	
			23MAY2011	YES	7:30	YES	19:30	
			24MAY2011	YES	7:30	YES	19:30	
			25MAY2011	YES	7:30	YES	19:30	
			26MAY2011	YES	7:30	YES	19:30	
			27MAY2011	YES	7:30	YES	19:30	
			28MAY2011	YES	7:45	YES	19:30	
			29MAY2011	YES	7:45	YES	19:30	
			30MAY2011	YES	7:30	YES	19:30	
			31MAY2011	YES	7:50	YES	19:30	
			01JUN2011	YES	7:50	YES	19:30	
			02JUN2011	YES	7:50	YES	19:30	
			03JUN2011	YES	7:50	YES	19:30	
			04JUN2011	YES	7:30	YES	19:45	
			05JUN2011	YES	7:30	YES	19:45	
			06JUN2011	YES	7:45	YES	20:00	
			07JUN2011	YES	7:45	YES	19:30	
			08JUN2011	YES	7:45	YES	19:30	
			09JUN2011	YES	7:30	YES	19:45	
			10JUN2011	YES	7:30	YES	19:45	
			11JUN2011	YES	7:30	YES	19:45	
			12JUN2011	YES	7:30	YES	19:45	
			13JUN2011	YES	7:30	YES	19:45	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	14JUN2011	YES	7:30	YES	19:45	
			15JUN2011	YES	7:20	YES	20:00	
			16JUN2011	YES	7:20	YES	20:00	
			17JUN2011	YES	7:30	YES	20:00	
			18JUN2011	YES	7:35	YES	20:00	
			19JUN2011	YES	7:35	YES	19:30	
			20JUN2011	YES	7:40	YES	19:30	
			21JUN2011	YES	7:40	YES	19:30	
			22JUN2011	YES	7:40	YES	19:30	
			23JUN2011	YES	7:40	YES	19:30	
			24JUN2011	YES	7:45	YES	20:00	
			25JUN2011	YES	7:45	YES	20:00	
			26JUN2011	YES	7:45	YES	20:00	
			27JUN2011	YES	7:30	YES	19:30	
			28JUN2011	YES	7:35	YES	19:30	
			29JUN2011	YES	7:36	YES	19:31	
			30JUN2011	YES	7:45	YES	19:45	
			01JUL2011	YES	7:50	YES	19:45	
			02JUL2011	YES	7:50	YES	19:45	
			03JUL2011	YES	7:30	YES	19:20	
			04JUL2011	YES	7:30	YES	19:20	
			05JUL2011	YES	7:30	YES	19:20	
			06JUL2011	YES	7:35	YES	19:20	
			07JUL2011	YES	7:35	YES	20:01	
			08JUL2011	YES	7:38	YES	20:01	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	09JUL2011	YES	7:20	YES	20:10	
			10JUL2011	YES	7:30	YES	19:40	
			11JUL2011	YES	7:30	YES	19:40	
			12JUL2011	YES	7:45	YES	19:30	
			13JUL2011	YES	7:45	YES	19:30	
			14JUL2011	YES	7:45	YES	19:30	
			15JUL2011	YES	7:45	YES	19:30	
			16JUL2011	YES	7:45	YES	19:30	
			17JUL2011	YES	7:45	YES	19:30	
			18JUL2011	YES	7:50	YES	19:30	
			19JUL2011	YES	7:45	YES	19:30	
			20JUL2011	YES	7:50	YES	19:30	
			21JUL2011	YES	7:20	YES	20:00	
			22JUL2011	YES	7:20	YES	20:00	
			23JUL2011	YES	7:30	YES	20:00	
			24JUL2011	YES	7:40	YES	20:00	
			25JUL2011	YES	7:40	YES	20:00	
			26JUL2011	YES	8:00	YES	20:00	
			27JUL2011	YES	7:40	YES	20:00	
			28JUL2011	YES	7:45	YES	20:00	
			29JUL2011	YES	8:00	YES	20:00	
			30JUL2011	YES	7:20	YES	19:30	
			31JUL2011	YES	7:30	YES	19:30	
			01AUG2011	YES	7:30	YES	19:30	
			02AUG2011	YES	7:30			

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	02AUG2011			YES	19:30	
			03AUG2011	YES	8:15	YES	19:30	
			04AUG2011	YES	8:15	YES	20:00	
			05AUG2011	YES	8:15	YES	20:00	
			06AUG2011	YES	8:20	YES	20:00	
			07AUG2011	YES	8:20	YES	20:05	
			08AUG2011	YES	8:25	YES	19:30	
			09AUG2011	YES	8:20	YES	19:45	
			10AUG2011	YES	8:15	YES	19:40	
			11AUG2011	YES	7:50	YES	20:00	
			12AUG2011	YES	7:50	YES	20:00	
			13AUG2011	YES	7:50	YES	20:00	
			14AUG2011	YES	7:50	YES	20:05	
			15AUG2011	YES	8:00	YES	20:05	
			16AUG2011	YES	8:05	YES	20:05	
			17AUG2011	YES	8:00	YES	20:01	
			18AUG2011	YES	8:00	YES	20:00	
			19AUG2011	YES	7:50	YES	20:00	
			20AUG2011	YES	7:30	YES	20:00	
			21AUG2011	YES	7:30	YES	19:45	
			22AUG2011	YES	7:40	YES	19:46	
			23AUG2011	YES	7:35	YES	19:55	
			24AUG2011	YES	7:45	YES	19:46	
			25AUG2011	YES	7:50	YES	19:55	
			26AUG2011	YES	8:00	YES	19:05	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	27AUG2011	YES	8:00	YES	19:30	
			28AUG2011	YES	7:45	YES	19:30	
			29AUG2011	YES	8:00	YES	20:00	
			30AUG2011	YES	8:00	YES	20:00	
			31AUG2011	YES	7:50	YES	20:05	
			01SEP2011	YES	7:30	YES	19:30	
			02SEP2011	YES	7:35	YES	19:35	
			03SEP2011	YES	7:40	YES	19:20	
			04SEP2011	YES	8:00	YES	19:40	
			05SEP2011	YES	8:00	YES	19:40	
			06SEP2011	YES	8:00	YES	19:40	
			07SEP2011		7:30	YES	20:00	
			08SEP2011		7:30	YES	20:00	
			09SEP2011		7:30	YES	20:00	
			10SEP2011		7:45	YES	20:00	
			11SEP2011		7:45	YES	20:00	
			12SEP2011		7:45	YES	20:01	
			13SEP2011		8:00	YES	19:50	
			14SEP2011		8:00	YES	19:50	
			15SEP2011		8:01	YES	19:50	
			16SEP2011	YES	7:50	YES	20:00	
			17SEP2011	YES	7:35	YES	20:00	
			18SEP2011	YES	7:35	YES	20:00	
			19SEP2011	YES	7:40	YES	20:00	
			20SEP2011	YES	7:43	YES	20:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	21SEP2011	YES	7:55	YES	20:00	
			22SEP2011	YES	7:35	YES	20:00	
			23SEP2011	YES	7:35	YES	20:00	
			24SEP2011	YES	7:35	YES	20:00	
			25SEP2011	YES	7:30	YES	20:00	
			26SEP2011	YES	7:30	YES	19:30	
			27SEP2011	YES	7:45	YES	19:40	
			28SEP2011	YES	7:45	YES	19:40	
			29SEP2011	YES	7:45	YES	19:45	
			30SEP2011	YES	7:30	YES	19:45	
			01OCT2011	YES	7:30	YES	19:45	
			02OCT2011	YES	7:55	YES	19:45	
			03OCT2011	YES	8:00	YES	19:55	
			04OCT2011	YES	7:50	YES	20:00	
			05OCT2011	YES	7:50	YES	20:00	
			06OCT2011	YES	7:50	YES	19:30	
			07OCT2011	YES	7:51	YES	19:35	
			08OCT2011	YES	7:55	YES	19:20	
			09OCT2011	YES	8:00	YES	20:00	
			10OCT2011	YES	8:00	YES	20:00	
			11OCT2011	YES	8:00	YES	20:00	
			12OCT2011	YES	8:00	YES	20:00	
			13OCT2011	YES	8:00	YES	20:00	
			14OCT2011	YES	8:00	YES	20:00	
			15OCT2011	YES	8:00	YES	20:01	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	16OCT2011	YES	7:50	YES	19:30	
			17OCT2011	YES	7:50	YES	19:30	
			18OCT2011	YES	7:50	YES	19:30	
			19OCT2011	YES	8:00	YES	19:35	
			20OCT2011	YES	8:00	YES	19:35	
			21OCT2011	YES	8:00	YES	19:38	
			22OCT2011	YES	7:30	YES	20:00	
			23OCT2011	YES	7:30	YES	19:30	
			24OCT2011	YES	7:40	YES	19:30	
			25OCT2011	YES	7:40	YES	19:32	
			26OCT2011	YES	8:00	YES	19:32	
			27OCT2011	YES	8:00	YES	19:45	
			28OCT2011	YES	7:40	YES	19:45	
			29OCT2011	YES	7:30	YES	20:00	
			30OCT2011	YES	7:30	YES	20:00	
			31OCT2011	YES	7:30	YES	20:00	
			01NOV2011	YES	7:35	YES	20:00	
			02NOV2011	YES	7:45	YES	20:00	
			03NOV2011	YES	7:45	YES	20:01	
			04NOV2011	YES	8:00	YES	20:05	
			05NOV2011	YES	8:00	YES	20:00	
			06NOV2011	YES	7:45	YES	20:10	
			07NOV2011	YES	7:45	YES	20:00	
			08NOV2011	YES	8:00	YES	19:05	
			09NOV2011	YES	7:30	YES	20:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	084	17	10NOV2011	YES	7:30	YES	20:00	
			11NOV2011	YES	7:40	YES	20:00	
			12NOV2011	YES	7:40	YES	20:00	
			13NOV2011	YES	7:30	YES	20:00	
			14NOV2011	YES	7:30	YES	19:55	
			15NOV2011	YES	7:40	YES	19:55	
			16NOV2011	YES	7:45	YES	19:55	
			17NOV2011	YES	7:50	YES	19:55	
			18NOV2011	YES	7:45	YES	20:00	
			19NOV2011	YES	7:45	YES	20:00	
			20NOV2011	YES	7:45	YES	20:00	
			21NOV2011	YES	7:50	YES	20:00	
			22NOV2011	YES	7:50			
	086	21	28OCT2010			YES	17:30	
			29OCT2010	YES	8:00	YES	18:00	
			30OCT2010	YES	8:00	YES	17:00	
			31OCT2010	YES	8:15	YES	17:00	
			01NOV2010	YES	7:15	YES	18:00	
			02NOV2010	YES	8:00	YES	18:00	
			03NOV2010	YES	8:00	YES	16:45	
			04NOV2010	YES	9:00	YES	17:00	
			05NOV2010	YES	7:10	YES	18:00	
			06NOV2010	YES	7:15	YES	18:30	
			07NOV2010	YES	8:00	NO		vergessen

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	08NOV2010	YES	7:30	YES	17:00	
			09NOV2010	YES	7:30	YES	17:00	
			10NOV2010	YES	7:30	YES	17:00	
			11NOV2010	YES	7:30	YES	17:30	
			12NOV2010	YES	7:30	YES	20:00	
			13NOV2010	YES	7:30	YES	17:00	
			14NOV2010	YES	7:30	YES	17:44	
			15NOV2010	YES	7:30	YES	16:45	
			16NOV2010	YES	7:30	YES	16:45	
			17NOV2010	YES	7:30	YES	16:45	
			18NOV2010	YES	7:30	YES	16:45	
			19NOV2010	YES	7:30	YES	16:45	
			20NOV2010	YES	7:30	YES	17:00	
			21NOV2010	YES	7:45	YES	17:00	
			22NOV2010	YES	7:45	YES	17:00	
			23NOV2010	YES	6:15			
			23NOV2010	YES		YES	17:00	
			24NOV2010	YES	7:00	YES	18:15	
			25NOV2010	YES	8:00	YES	17:00	
			26NOV2010	YES	8:00	YES	17:00	
			27NOV2010	YES	7:00	YES	17:00	
			28NOV2010	YES	7:00	YES	18:00	
			29NOV2010	YES	7:00	YES	17:00	
			30NOV2010	YES	7:00	YES	18:15	
			02DEC2010	YES	7:30	YES	18:15	PROXEN

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	03DEC2010	YES	7:15	YES	17:00	
			04DEC2010	YES	7:20	YES	16:30	
			05DEC2010	YES	7:20	YES	17:00	
			06DEC2010	YES	7:30	YES	18:00	
			07DEC2010	YES	7:20	YES	17:00	
			08DEC2010	YES	7:30	YES	17:00	
			09DEC2010	YES	7:45	YES	17:00	
			10DEC2010	YES	7:45	YES	16:30	
			11DEC2010	YES	7:45	YES	17:30	
			12DEC2010	YES	7:30	YES	16:30	
			13DEC2010	YES	7:00	YES	17:00	
			14DEC2010	YES	7:15	YES	18:30	
			15DEC2010	YES	7:00	YES	17:00	
			16DEC2010	YES	7:15	YES	17:00	
			17DEC2010	YES	8:00	YES	17:00	
			18DEC2010	YES	8:00	YES	17:00	
			19DEC2010	YES	7:30	YES	17:00	
			20DEC2010	YES	7:45	YES	17:00	
			21DEC2010	YES	8:00	YES	17:00	
			22DEC2010	YES	7:00	NO		War nicht zu Haus, hab die Tabletten nicht mitgehabt.
			23DEC2010	YES	7:45	YES	18:30	
			24DEC2010	YES	7:15	YES	18:30	
			25DEC2010	YES	7:15	YES	17:00	
			26DEC2010	YES	7:30	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	27DEC2010	YES	7:30	YES	17:00	
			28DEC2010	YES	7:45	YES	18:30	
			29DEC2010	YES	7:30	YES	19:00	
			30DEC2010	YES	8:00	YES	17:10	
			31DEC2010	YES	7:30	YES	17:00	
			01JAN2011	YES	7:30	YES	17:00	
			01JAN2011	YES	7:30	YES	17:00	
			02JAN2011	YES	7:15	YES	17:00	
			03JAN2011	YES	7:30	YES	17:00	
			04JAN2011	YES	8:00	YES	17:00	
			05JAN2011	YES	7:15	YES	17:00	
			06JAN2011	YES	6:48	YES	20:00	
			07JAN2011	YES	7:30	YES	17:00	
			08JAN2011	YES	8:00	YES	17:00	
			09JAN2011	YES	7:15	YES	18:35	
			10JAN2011	YES	7:30	YES	17:00	
			11JAN2011	YES	7:00	YES	17:00	
			12JAN2011	YES	7:15	YES	17:00	
			13JAN2011	YES	7:15	YES	17:10	
			14JAN2011	YES	7:15	YES	17:00	
			15JAN2011	YES	7:15	YES	17:00	
			16JAN2011	YES	7:15	YES	17:00	
			17JAN2011	YES	8:00	YES	18:15	
			18JAN2011			YES	17:50	
			19JAN2011	YES	7:00	YES	17:10	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	20JAN2011	YES	7:30	YES	16:30	
			21JAN2011	YES	7:30	YES	16:30	
			22JAN2011	YES	7:15	YES	17:10	
			23JAN2011	YES	7:15	YES	19:00	
			24JAN2011	YES	7:15	YES	17:00	
			25JAN2011	YES	6:45	YES	17:00	
			26JAN2011	YES	7:15	YES	17:00	
			27JAN2011	YES	6:45	YES	17:30	
			28JAN2011	YES	7:15	YES	17:05	
			29JAN2011	YES	7:35	YES	17:30	
			30JAN2011	YES	7:30	YES	17:00	
			31JAN2011	YES	7:35	YES	17:00	
			02FEB2011	YES	7:00	YES	17:00	
			03FEB2011	YES	7:30	YES	17:30	
			04FEB2011	YES	7:15	YES	17:00	
			05FEB2011	YES	7:15	YES	16:45	
			06FEB2011	YES	7:00	YES	17:15	
			07FEB2011	YES	7:45	YES	17:00	
			08FEB2011	YES	7:45	YES	17:15	
			09FEB2011	YES	7:15	YES	17:15	
			10FEB2011	YES	7:30	YES	17:15	
			11FEB2011	YES	7:30	YES	17:00	
			12FEB2011	YES	7:40	YES	17:30	
			13FEB2011	YES	7:40	YES	17:00	
			14FEB2011	YES	7:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	15FEB2011	YES	7:20	YES	17:00	
			16FEB2011	YES	7:10	YES	17:00	
			17FEB2011	YES	8:00	YES	17:00	
			18FEB2011	YES	7:45	YES	17:00	
			19FEB2011	YES	7:30	YES	17:30	
			20FEB2011	YES	7:10	YES	17:10	
			21FEB2011	YES	8:00	YES	17:10	
			22FEB2011	YES	8:00	YES	17:10	
			23FEB2011	YES	7:00	YES	16:50	
			24FEB2011	YES	8:00	YES	17:00	
			25FEB2011	YES	7:30	YES	16:30	
			26FEB2011	YES	7:15	YES	16:30	
			27FEB2011	YES	8:00	YES	16:15	
			28FEB2011	YES	7:20	YES	16:30	
			01MAR2011	YES	7:45	YES	17:00	
			02MAR2011	YES	7:10	YES	17:00	
			03MAR2011	YES	7:15	YES	18:30	
			04MAR2011	YES	7:30	YES	17:00	
			05MAR2011	YES	7:30	YES	17:00	
			06MAR2011	YES	7:15	YES	17:00	
			07MAR2011	YES	7:30	YES	17:15	
			08MAR2011	YES	7:30	YES	17:00	
			09MAR2011	YES	7:00	YES	17:00	
			10MAR2011	YES	7:15	YES	17:00	
			11MAR2011	YES	7:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	12MAR2011	YES	7:15	YES	17:00	
			13MAR2011	YES	7:15	YES	17:30	
			14MAR2011	YES	8:00	YES	17:00	
			15MAR2011	YES	7:00	YES	17:10	
			16MAR2011	YES	7:00	YES	17:00	
			17MAR2011	YES	7:25	YES	17:00	
			18MAR2011	YES	7:25	YES	17:00	
			19MAR2011	YES	7:15	YES	17:00	
			20MAR2011	YES	7:10	YES	17:00	
			21MAR2011	YES	6:45	YES	17:00	
			22MAR2011	YES	7:35	YES	17:15	
			23MAR2011	YES	7:00	YES	17:10	
			24MAR2011	YES	7:00	YES	18:30	
			25MAR2011	YES	7:15	YES	17:00	
			26MAR2011	YES	7:00	YES	17:00	
			27MAR2011	YES	6:45	YES	17:10	
			28MAR2011	YES	7:00	YES	17:30	
			29MAR2011	YES	7:00	YES	17:00	
			30MAR2011	YES	7:00	YES	17:00	
			31MAR2011	YES	7:00	NO	18:00	war nicht zu Hause
			01APR2011	YES	7:30	YES	18:00	
			02APR2011	YES	8:00	YES	17:30	
			03APR2011	YES	7:00	YES	18:00	
			04APR2011	YES	7:10	YES	17:00	
			05APR2011	YES	7:20	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	06APR2011	YES	7:20	YES	17:40	
			07APR2011	YES	7:30	YES	17:00	
			08APR2011	YES	7:15	YES	17:10	
			09APR2011	YES	7:30	NO	18:00	
			10APR2011	YES	7:15	YES	17:10	
			11APR2011	YES	7:15	YES	17:10	
			12APR2011	YES	7:00			
			12APR2011			NO		war nicht daheim
			13APR2011	YES	7:15	YES	18:00	
			14APR2011	YES	7:25	YES	17:00	
			15APR2011	YES	7:30	YES	18:30	
			16APR2011	YES	7:45	YES	18:45	
			17APR2011	YES	7:15	YES	17:00	
			18APR2011	YES	7:25	YES	17:30	
			19APR2011	YES	7:10	YES	17:00	
			20APR2011	YES	7:00	YES	17:10	
			21APR2011	YES	7:10	YES	17:00	
			22APR2011	YES	7:15	YES	17:10	
			23APR2011	YES	7:30	YES	17:05	
			24APR2011	YES	7:15	YES	17:25	
			25APR2011	YES	6:50	YES	17:00	
			26APR2011	YES	7:10	YES	17:00	
			27APR2011	YES	7:15	YES	17:00	
			28APR2011	YES	7:30	YES	17:00	
			29APR2011	YES	7:15	YES	17:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	30APR2011	YES	6:30	YES	17:00	
			01MAY2011	YES	6:50	YES	17:00	
			02MAY2011	YES	7:10	YES	17:00	
			03MAY2011	YES	7:10	YES	17:00	
			04MAY2011	YES	7:15	YES	17:00	
			05MAY2011	YES	7:30	YES	18:00	
			06MAY2011	YES	7:30	YES	18:00	
			07MAY2011	YES	7:30	YES	17:00	
			08MAY2011	YES	7:30	YES	18:30	
			09MAY2011	YES	7:00	YES	17:00	
			10MAY2011	YES	6:40	YES	20:00	
			11MAY2011	YES	7:00	YES	17:00	
			12MAY2011	YES	7:00	YES	17:00	
			13MAY2011	YES	7:40	YES	17:00	
			14MAY2011		7:40	YES	17:00	
			15MAY2011	YES	7:30	YES	18:00	
			16MAY2011	YES	7:30	YES	17:00	
			17MAY2011	YES	7:30	YES	17:00	
			18MAY2011	YES	7:20		17:15	
			19MAY2011	YES	6:40	YES	17:00	
			20MAY2011	YES	6:45	YES	17:10	
			21MAY2011		7:50	YES	17:00	
			22MAY2011	YES	7:00	YES	17:00	
			23MAY2011	YES	7:30	YES	17:00	
			24MAY2011	YES	7:15	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	25MAY2011	YES	7:15	YES	17:00	
			26MAY2011	YES	6:45	YES	17:10	
			27MAY2011	YES	7:20	YES	17:00	
			28MAY2011	YES	7:20	YES	17:00	
			29MAY2011	YES	7:15	YES	17:00	
			30MAY2011	YES	6:45	YES	17:00	
			31MAY2011	YES	7:10	YES	17:00	
			01JUN2011	YES	7:20	YES	17:00	
			02JUN2011	YES	7:20	YES	17:00	
			03JUN2011	YES	7:00	YES	17:00	
			04JUN2011	YES	8:00	YES	18:30	
			05JUN2011	YES	7:30	YES	17:30	
			06JUN2011	YES	7:30	YES	18:00	
			07JUN2011	YES	6:45	YES	17:00	
			08JUN2011	YES	7:40	YES	17:30	
			09JUN2011	YES	7:50	YES	17:30	
			10JUN2011	YES	7:30	YES	19:00	
			11JUN2011	YES	7:45		16:00	
			12JUN2011	YES	7:45	YES	17:30	
			13JUN2011	YES	7:10	YES	17:00	
			14JUN2011	YES	7:30	YES	18:00	
			15JUN2011	YES	7:30	YES	21:00	
			16JUN2011	YES	7:15	YES	18:00	
			17JUN2011	YES	6:15	YES	18:00	
			18JUN2011	YES	8:00	YES	17:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	19JUN2011	YES	8:00	YES	18:35	
			20JUN2011	YES	7:15	YES	17:00	
			21JUN2011	YES	7:35	YES	17:00	
			22JUN2011	YES	6:50	YES	18:00	
			23JUN2011	YES	7:00	YES	18:00	
			24JUN2011	YES	7:00	YES	17:00	
			25JUN2011	YES	7:45	YES	17:00	
			26JUN2011	YES	7:00	YES	17:00	
			27JUN2011	YES	6:10	YES	20:00	
			28JUN2011	YES	6:15	YES	17:20	
			29JUN2011	YES	6:50	YES	17:45	
			30JUN2011	YES	7:30	YES	17:45	
			01JUL2011	YES	7:20	YES	17:00	
			02JUL2011	YES	7:20	YES	16:35	
			03JUL2011	YES	7:20	YES	17:00	
			05JUL2011	NO		YES	18:00	
			06JUL2011	YES	7:10	YES	18:00	
			07JUL2011	YES	7:10	YES	17:30	
			08JUL2011	YES	7:45	YES	17:00	
			09JUL2011	YES	6:30	YES	17:25	
			10JUL2011	YES	7:30	YES	17:45	
			11JUL2011	YES	7:30	YES	17:05	
			12JUL2011	YES	7:05	YES	17:25	
			14JUL2011	YES	6:55	YES	17:30	
			15JUL2011	YES	7:00	YES	16:40	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	16JUL2011	YES	8:00	YES	19:00	
			17JUL2011	YES	7:00	YES	17:00	
			18JUL2011	YES	7:00	YES	17:00	
			19JUL2011	YES	7:00	YES	19:00	
			20JUL2011	YES	7:00		19:00	
			21JUL2011	YES	7:00	YES	17:00	
			22JUL2011	YES	7:50	YES	16:40	
			23JUL2011	YES	7:45			
			24JUL2011	YES	7:30	YES	20:00	
			25JUL2011	YES	7:10	YES	17:15	
			26JUL2011	YES	8:45	YES	17:45	
			27JUL2011	YES	7:00	YES	17:00	
			28JUL2011	YES	7:05	YES	17:00	
			29JUL2011	YES	8:00	YES	17:00	
			30JUL2011	YES	7:00	YES	17:00	
			31JUL2011	YES	7:10	YES	17:00	
			01AUG2011	YES	7:40	YES	17:00	
			02AUG2011			YES	16:30	
			03AUG2011	YES	7:50	YES	17:00	
			04AUG2011	YES	7:10	YES	18:00	
			05AUG2011	YES	7:00	YES	18:00	
			06AUG2011	YES	6:45	YES	18:00	
			07AUG2011	YES	6:45	YES	17:05	
			08AUG2011	YES	7:10	YES	17:10	
			09AUG2011	YES	7:15	YES	19:00	

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach

Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	10AUG2011	YES	7:15	YES	17:30	
			11AUG2011	YES	7:00	YES	17:00	
			12AUG2011	YES	7:15	YES	17:00	
			13AUG2011	YES	8:10	YES	17:40	
			14AUG2011	YES	7:30	YES	20:00	
			15AUG2011	YES	7:15	YES	17:00	
			16AUG2011	YES	7:30	YES	17:00	
			17AUG2011	YES	7:00	YES	18:00	
			18AUG2011	YES	7:15	YES	18:30	
			19AUG2011	YES	7:45	YES	18:00	
			20AUG2011	YES	8:10	YES	19:00	
			21AUG2011	YES	7:45	YES	17:05	
			22AUG2011	YES	7:30	YES	17:00	
			23AUG2011	YES	7:25	YES	17:00	
			24AUG2011	YES	7:10	YES	18:30	
			25AUG2011	YES	7:30	YES	17:00	
			26AUG2011	YES	8:00	YES	17:00	
			27AUG2011	YES	8:00	YES	17:00	
			28AUG2011	YES	7:30	YES	17:30	
			29AUG2011	YES	7:30	YES	17:10	
			30AUG2011	YES	7:40	YES	17:00	
			31AUG2011	YES	7:00	YES	18:00	
			01SEP2011	YES	7:15	YES	17:00	
			02SEP2011	YES	7:00	YES	17:00	
			03SEP2011	YES	7:15	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	04SEP2011	YES	7:30	YES	19:00	
			05SEP2011	YES	7:30	YES	17:00	
			06SEP2011	YES	7:45	YES	18:25	
			07SEP2011	YES	7:00	YES	18:00	
			08SEP2011	YES	7:10	YES	17:15	
			09SEP2011	YES	8:00	YES	17:00	
			10SEP2011	YES	7:10	YES	17:00	
			11SEP2011	YES	7:10	YES	17:00	
			12SEP2011	YES	7:10	YES	17:40	
			13SEP2011	YES	7:45	YES	17:00	
			14SEP2011	YES	7:00	YES	17:15	
			15SEP2011			YES	17:10	
			16SEP2011	YES	7:30	YES	17:00	
			17SEP2011	YES	7:30	YES	17:00	
			18SEP2011	YES	7:30	YES	18:45	
			19SEP2011	YES	7:30	YES	18:45	
			20SEP2011	YES	8:00	YES	16:10	
			21SEP2011	YES	7:30	YES	16:45	
			22SEP2011	YES	7:30	YES	17:00	
			23SEP2011	YES	8:00	YES	17:15	
			24SEP2011	YES		YES	17:30	
			25SEP2011	YES	7:25	YES	17:10	
			26SEP2011		7:15	YES	17:30	
			27SEP2011	YES	7:45	YES	17:00	
			28SEP2011	YES	7:30	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	29SEP2011	YES	7:45	YES	17:00	
			30SEP2011	YES	7:10	YES	17:00	
			01OCT2011	YES	7:30	YES	17:00	
			02OCT2011	YES	7:30	YES	17:00	
			03OCT2011	YES	7:30	YES	17:00	
			04OCT2011	YES	8:00	YES	17:00	
			05OCT2011	YES	7:45	YES	17:00	
			06OCT2011	YES	7:45	YES	17:00	
			07OCT2011	YES	7:30	YES	17:00	
			08OCT2011	YES	7:45	YES	17:00	
			09OCT2011	YES	7:30	YES	17:00	
			10OCT2011	YES	7:30	YES	17:00	
			11OCT2011	YES	7:45	YES	17:00	
			12OCT2011	YES	7:30	YES	17:45	
			13OCT2011	YES	7:30	YES	17:00	
			14OCT2011	YES	8:00	YES	17:00	
			15OCT2011	YES	8:00	YES	17:00	
			16OCT2011	YES	7:30	YES	17:10	
			17OCT2011	YES	7:50	YES	17:10	
			18OCT2011	YES	7:40	YES	17:00	
			19OCT2011	YES	7:30	YES	17:00	
			20OCT2011	YES	7:30	YES	17:00	
			21OCT2011	YES	7:30	YES	17:00	
			22OCT2011	YES	7:30	YES	17:00	
			23OCT2011	YES	7:15	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	086	21	24OCT2011	YES	7:30	YES	18:00	
			25OCT2011	YES	6:45			
			13JUL2012	YES	7:00	YES	18:10	
	088	16	10DEC2010	YES	6:30	YES	17:15	
			11DEC2010	YES	7:30	YES	17:45	
			12DEC2010	YES	7:20	YES	18:00	
			13DEC2010	YES	7:00	YES	17:00	
			14DEC2010	YES	7:15		17:00	
			15DEC2010	YES	7:30	YES	17:00	
			16DEC2010	YES	7:30	YES	17:15	
			17DEC2010	YES	6:50	YES	16:45	
			18DEC2010	YES	7:30	YES	16:45	
			19DEC2010	YES	7:00	YES	16:30	
			20DEC2010	YES	7:15	YES	16:45	
			21DEC2010	YES	7:30	YES	17:00	
			22DEC2010	YES	7:30	YES	16:45	
			23DEC2010	YES	7:15	YES	17:15	
			24DEC2010	YES	7:20	YES	18:00	
			25DEC2010	YES	7:00	YES	17:00	
			26DEC2010	YES	7:45	YES	17:00	
			27DEC2010	YES	7:30	YES	17:00	
			28DEC2010	YES	7:40	YES	16:45	
			29DEC2010	YES	7:50	YES	17:00	
			30DEC2010	YES	7:15	YES	17:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	31DEC2010	YES	7:30	YES	17:30	
			01JAN2011	YES	4:00	YES	16:45	
			02JAN2011	YES	7:50	YES	17:00	
			03JAN2011	YES	7:15	YES	17:30	
			04JAN2011	YES	7:15			
			04JAN2011	YES	7:15	YES	17:00	
			05JAN2011	YES	7:20	YES	16:30	
			06JAN2011	YES	7:30	YES	17:15	
			07JAN2011	YES	7:20	YES	17:30	
			08JAN2011	YES	7:20	YES	16:45	
			09JAN2011	YES	8:10	YES	17:15	
			10JAN2011	YES	7:10	YES	16:55	
			11JAN2011	YES	7:40	YES	17:00	
			12JAN2011	YES	7:15	YES	16:50	
			13JAN2011	YES	7:00	YES	17:00	
			14JAN2011	YES	7:10	YES	16:50	
			15JAN2011	YES	7:40	YES	17:00	
			16JAN2011	YES	7:20	YES	17:15	
			17JAN2011	YES	7:10	YES	17:10	
			18JAN2011	YES	7:30	YES	17:00	
			19JAN2011	YES	7:15	YES	16:50	
			20JAN2011	YES	7:20	YES	17:10	
			21JAN2011	YES	7:15	YES	17:15	
			22JAN2011	YES	7:30	YES	17:20	
			23JAN2011	YES	7:20	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	24JAN2011	YES	7:10	YES	16:50	
			25JAN2011	YES	7:40	YES	16:45	
			26JAN2011	YES	7:10	YES	17:30	
			27JAN2011	YES	7:30	YES	17:10	
			28JAN2011	YES	7:10	YES	17:00	
			29JAN2011	YES	7:30	YES	16:50	
			30JAN2011	YES	7:30	YES	17:15	
			31JAN2011	YES	7:10	YES	17:20	
			01FEB2011	YES	7:30	YES	17:10	
			02FEB2011	YES	7:15	YES	17:20	
			03FEB2011	YES	7:30	YES	18:10	
			04FEB2011	YES	7:15	YES	17:15	
			05FEB2011	YES	7:45	YES	17:30	
			06FEB2011	YES	7:30	YES	18:10	
			07FEB2011	YES	7:15	YES	17:00	
			08FEB2011	YES	7:30	YES	17:20	
			09FEB2011	YES	7:10	YES	18:00	
			10FEB2011	YES	7:50	YES	17:10	
			11FEB2011	YES	7:20	YES	17:30	
			12FEB2011	YES	7:45	YES	17:10	
			13FEB2011	YES	7:30	YES	17:50	
			14FEB2011	YES	7:20	YES	18:20	
			15FEB2011	YES	7:30	YES	17:45	
			16FEB2011	YES	7:20	YES	17:20	
			17FEB2011	YES	7:30	YES	17:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	18FEB2011	YES	7:15	YES	17:30	
			19FEB2011	YES	7:40	YES	17:20	
			20FEB2011	YES	7:30	YES	18:10	
			21FEB2011	YES	7:15	YES	18:00	
			22FEB2011	YES	7:30	YES	17:20	
			23FEB2011	YES	7:15	YES	17:30	
			24FEB2011	YES	7:20	YES	17:55	
			25FEB2011	YES	7:20	YES	18:00	
			26FEB2011	YES	7:20	YES	17:40	
			27FEB2011	YES	7:40	YES	17:30	
			28FEB2011	YES	7:50	YES	17:40	
			01MAR2011	YES	7:00			
			01MAR2011			YES	17:40	
			02MAR2011	YES	7:15	YES	17:50	
			03MAR2011	YES	7:30	YES	18:10	
			04MAR2011	YES	7:15	YES	17:10	
			05MAR2011	YES	7:40	YES	18:05	
			06MAR2011	YES	7:30	YES	17:20	
			07MAR2011	YES	7:15	YES	17:30	
			08MAR2011	YES	7:30	YES	17:10	
			09MAR2011	YES	7:15	YES	17:05	
			10MAR2011	YES	7:35	YES	16:55	
			11MAR2011	YES	7:15	YES	17:00	
			12MAR2011	YES	7:30	YES	18:20	
			13MAR2011	YES	7:30	YES	18:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	14MAR2011	YES	7:15	YES	17:10	
			15MAR2011	YES	7:25	YES	17:35	
			16MAR2011	YES	7:15	YES	17:10	
			17MAR2011	YES	7:25	YES	17:35	
			18MAR2011	YES	7:15	YES	17:00	
			19MAR2011	YES	7:35	YES	18:10	
			20MAR2011	YES	7:30	YES	18:20	
			21MAR2011	YES	7:15	YES	17:50	
			22MAR2011	YES	7:30	YES	17:25	
			23MAR2011	YES	7:15	YES	17:30	
			24MAR2011	YES	7:30	YES	18:00	
			25MAR2011	YES	7:15	YES	17:40	
			26MAR2011	YES	7:25	YES	7:30	
			27MAR2011	YES	7:30	NO		Waren unterwegs vergessen mitzunehmen
			28MAR2011	YES	7:15	YES	17:30	
			29MAR2011	YES	7:30	YES	18:10	
			30MAR2011	YES	7:15	YES	17:40	
			31MAR2011	YES	7:35	YES	17:15	
			01APR2011	YES	7:15	YES	17:35	
			02APR2011	YES	7:25			
			03APR2011	YES	8:00	YES	17:00	Weint immer öfter mit der Bemerkung "ich bin traurig"
			04APR2011	YES	7:15	YES	18:10	
			05APR2011	YES	7:25	YES	17:40	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	06APR2011	YES	7:15	YES	17:30	Nimmt zum Essen immer mehr die Finger und kann nicht mehr mit Messer und Gabel essen auch wenn man es ihr zeigt
			07APR2011	YES	7:30	YES	17:50	
			08APR2011	YES	7:15	YES	18:10	
			09APR2011	YES	7:35	YES	18:20	
			10APR2011	YES	7:20	YES	17:40	
			11APR2011	YES	7:15	YES	17:35	
			12APR2011	YES	7:05	YES	17:10	Weint auf der Straße, wenn sie kleine Kinder sieht die weinen
			13APR2011	YES	7:15	YES	17:30	
			14APR2011	YES	7:15	YES	17:20	
			15APR2011	YES	6:55	YES	16:30	
			16APR2011	YES	7:40	YES	17:50	
			17APR2011	YES	7:30	YES	18:20	Weint neuerdings auch, wenn sie sich freut
			18APR2011	YES	7:15	YES	16:55	
			19APR2011	YES	7:30	YES	17:35	
			20APR2011	YES	7:10	YES	17:30	
			21APR2011	YES	7:25	YES	17:50	
			22APR2011	YES	7:20	YES	18:00	Winkt fremden Leuten zu und sagt "die freuen sich doch"
			23APR2011	YES	7:30	YES	17:50	
			24APR2011	YES	7:20	YES	17:45	
			25APR2011	YES	7:25	YES	18:30	
			26APR2011	YES	7:20	YES	17:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	27APR2011	YES	7:15	YES	16:50	
			28APR2011	YES	7:30	YES	17:10	Will nach Versuchen mehrerer Tage nicht mehr lesen + rätseln
			29APR2011	YES	7:15	YES	17:40	
			30APR2011	YES	7:25	YES	18:10	Fällt das Schreiben schwer, viele Fehler
			01MAY2011	YES	7:30	YES	18:20	
			02MAY2011	YES	7:15	YES	17:15	
			03MAY2011	YES	7:25	YES	17:20	
			04MAY2011	YES	7:15	YES	17:50	
			05MAY2011	YES	7:10	YES	18:10	
			06MAY2011	YES	7:15	YES	17:30	
			07MAY2011	YES	7:35	YES	18:05	
			08MAY2011	YES	7:30	YES	17:50	Will ihre Zähne nicht mehr putzen, ich muss sie dazu zwingen
			09MAY2011	YES	7:15	YES	16:55	Will ihre Zähne nicht mehr putzen, ich muss sie dazu zwingen
			10MAY2011	YES	7:35	YES	18:10	Will ihre Zähne nicht mehr putzen, ich muss sie dazu zwingen
			11MAY2011	YES	7:15	YES	17:00	Will ihre Zähne nicht mehr putzen, ich muss sie dazu zwingen
			12MAY2011	YES	7:25	YES	17:20	
			13MAY2011	YES	7:00	YES	17:30	
			14MAY2011	YES	7:40	YES	18:00	
			15MAY2011	YES	7:30	YES	18:10	
			16MAY2011	YES	7:35	YES	17:55	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	17MAY2011	YES	7:30	YES	17:20	
			18MAY2011	YES	7:00	YES	17:50	
			19MAY2011	YES	6:45			
			19MAY2011			YES	17:35	
			20MAY2011	YES	7:15	YES	18:10	
			21MAY2011	YES	7:25	YES	18:45	
			22MAY2011	YES	7:20	YES	18:20	
			23MAY2011	YES	7:15	YES	17:40	
			24MAY2011	YES	7:10	YES	18:00	
			25MAY2011	YES	7:15	YES	17:40	
			26MAY2011	YES	7:10	YES	17:30	
			27MAY2011	YES	7:15	YES	18:20	
			28MAY2011	YES	7:20	YES	19:10	
			29MAY2011	YES	7:30	YES	18:20	
			30MAY2011	YES	7:10	NO		unterwegs
			31MAY2011	YES	6:55	YES	17:35	
			01JUN2011	YES	7:10	YES	17:10	
			02JUN2011	YES	7:25	YES	18:05	
			03JUN2011	YES	7:05	YES	17:55	
			04JUN2011	YES	7:20	YES	18:10	
			05JUN2011	YES	7:25	YES	18:00	
			06JUN2011	YES	7:00	YES	17:30	
			07JUN2011	YES	6:30	YES	17:45	
			08JUN2011	YES	7:10	YES	18:00	
			09JUN2011	YES	7:20	YES	18:15	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	10JUN2011	YES	6:50	YES	17:10	
			11JUN2011	YES	7:10	YES	17:30	
			12JUN2011	YES	7:35	YES	18:10	
			13JUN2011	YES	7:20	YES	19:00	
			14JUN2011	YES	7:15	YES	18:25	
			15JUN2011	YES	7:10	YES	17:30	
			16JUN2011	YES	7:00	YES	17:40	
			17JUN2011	YES	7:15	YES	17:25	
			18JUN2011	YES	7:20	YES	18:10	Will kein Haarlack oder Parfüm, alles stinkt bei ihr.
			19JUN2011	YES	7:05	YES	18:50	
			20JUN2011	YES	7:00	YES	17:10	
			21JUN2011	YES	7:00	YES	17:50	
			22JUN2011	YES	7:00	YES	18:10	
			23JUN2011	YES	7:05	YES	17:20	
			24JUN2011	YES	7:00	YES	17:30	
			25JUN2011	YES	7:20	YES	17:50	Will nicht mehr alleine schlafen gehen wenn ich mal länger als sie aufbleiben will.
			26JUN2011	YES	7:00	YES	18:10	
			27JUN2011	YES	7:00	YES	17:40	
			28JUN2011	YES	6:50	YES	17:30	Wird immer schmerzempfindlicher eine leichte Berührung reicht schon.
			29JUN2011	YES	7:05	YES	16:50	
			30JUN2011	YES	7:00	YES	17:35	
			01JUL2011	YES	7:00	YES	16:50	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	02JUL2011	YES	7:05	YES	18:10	
			03JUL2011	YES	7:20	YES	18:20	
			04JUL2011	YES	7:00	YES	17:30	Spricht immer öfter fremde Menschen an, singt was vor.
			05JUL2011	YES	7:00	YES	17:40	
			06JUL2011	YES	7:00	YES	17:30	
			07JUL2011	YES	7:00	YES	17:25	
			08JUL2011	YES	7:00	YES	17:25	Braucht generell Hilfe bei der Körperpflege.
			09JUL2011	YES	7:30	YES	18:20	Weiß nichts mit der Zahnbürste anzufangen.
			10JUL2011	YES	7:20	YES	17:50	
			11JUL2011	YES	7:00	YES	17:10	
			12JUL2011	YES	7:00	YES	18:10	Kann sich kaum noch ohne Hilfe aus- und ankleiden.
			13JUL2011	YES	7:00	YES	17:40	
			14JUL2011	YES	7:00	YES	17:30	
			15JUL2011	YES	7:00	YES	18:05	Findet immer öfter die Bezeichnung für Gegenstände nicht. Bezeichnet sie als das Ding, die Dinger.
			16JUL2011	YES	7:20	YES	17:40	
			17JUL2011	YES	7:15	YES	18:20	
			18JUL2011	YES	7:00	YES	17:30	
			19JUL2011	YES	7:00	YES	17:30	
			20JUL2011	YES	7:00	YES	18:00	
			21JUL2011	YES	7:00	YES	17:50	
			22JUL2011	YES	7:00	YES	18:05	
			23JUL2011	YES	7:15	YES	18:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	24JUL2011	YES	7:20	YES	19:05	
			25JUL2011	YES	7:00	YES	17:40	
			26JUL2011	YES	7:20	YES	17:00	
			27JUL2011	YES	7:00	YES	17:00	
			28JUL2011	YES	7:00	YES	17:10	
			29JUL2011	YES	7:00	YES	17:00	
			30JUL2011	YES	7:00	YES	17:20	
			31JUL2011	YES	7:00	YES	17:25	
			01AUG2011	YES	7:00	YES	17:20	
			02AUG2011	YES	7:00	YES	17:30	
			03AUG2011	YES	7:00	YES	17:20	
			04AUG2011	YES	7:00	YES	17:25	
			05AUG2011	YES	7:00	YES	17:30	
			06AUG2011	YES	7:00	YES	17:40	
			07AUG2011	YES	7:00	YES	17:25	
			08AUG2011	YES	7:00	YES	17:30	Wird immer hemmungsloser, bedient sich von fremden Tellern und ißt die Kuchenkrümel vom abgestellten Geschirr.
			09AUG2011	YES	7:00	YES	17:30	
			10AUG2011	YES	7:00	YES	17:30	
			11AUG2011	YES	7:00	YES	17:20	
			12AUG2011	YES	7:00	YES	17:30	
			13AUG2011	YES	7:00	YES	17:30	
			14AUG2011	YES	7:00	YES	17:30	
			15AUG2011	YES	7:00	YES	17:25	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	16AUG2011	YES	7:00	YES	17:30	
			17AUG2011	YES	7:00	YES	17:20	
			18AUG2011	YES	7:00	YES	17:30	
			19AUG2011	YES	7:00	YES	17:30	
			20AUG2011	YES	7:00	YES	17:25	
			21AUG2011	YES	7:00	YES	17:30	
			22AUG2011	YES	7:00	YES	17:30	
			23AUG2011	YES	7:00	YES	17:00	
			24AUG2011	YES	7:20	YES	17:35	
			25AUG2011	YES	7:00	YES	17:30	
			26AUG2011	YES	7:00	YES	17:10	
			27AUG2011	YES	7:10	YES	17:50	
			28AUG2011	YES	7:20	YES	17:40	
			29AUG2011	YES	6:50			
			29AUG2011			YES	17:15	
			30AUG2011	YES	7:00	YES	17:30	
			31AUG2011	YES	7:00	YES	17:00	
			01SEP2011	YES	6:30	YES	17:10	
			02SEP2011	YES	7:00	YES	17:30	
			03SEP2011	YES	7:20	YES	18:05	
			04SEP2011	YES	7:30	YES	17:50	
			05SEP2011	YES	7:00	YES	17:20	
			06SEP2011	YES	7:00	YES	17:30	
			07SEP2011	YES	7:00	YES	17:20	
			08SEP2011	YES	6:20	YES	17:35	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	09SEP2011	YES	7:00	YES	16:50	
			10SEP2011	YES	7:20	YES	18:10	
			11SEP2011	YES	7:30	YES	17:50	
			12SEP2011	YES	7:00	YES	17:10	
			13SEP2011	YES	7:00	YES	17:00	
			14SEP2011	YES	7:00	YES	17:20	
			15SEP2011	YES	7:00	YES	16:55	
			16SEP2011	YES	7:00	YES	17:10	
			17SEP2011	YES	7:15	YES	18:05	
			18SEP2011	YES	7:35	YES	17:40	
			19SEP2011	YES	7:00	YES	17:10	
			20SEP2011	YES	6:50	YES	17:00	
			21SEP2011	YES	6:55	YES	17:30	
			22SEP2011	YES	7:00	YES	17:20	
			23SEP2011	YES	6:55	YES	17:25	
			24SEP2011	YES	7:15	YES	18:10	
			25SEP2011	YES	7:20	YES	17:50	
			26SEP2011	YES	7:00	YES	17:30	
			27SEP2011	YES	7:00	YES	17:10	
			28SEP2011	YES	7:00	YES	17:25	
			29SEP2011	YES	7:00	YES	17:00	
			30SEP2011	YES	7:00	YES	17:40	
			01OCT2011	YES	7:20	YES	17:10	
			02OCT2011	YES	7:15	YES	17:55	
			03OCT2011	YES	7:20	YES	17:10	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	04OCT2011	YES	7:00	YES	17:05	
			05OCT2011	YES	7:00	YES	17:00	
			06OCT2011	YES	7:00	YES	17:10	
			07OCT2011	YES	7:00	YES	16:55	
			08OCT2011	YES	7:10	YES	17:55	
			09OCT2011	YES	7:25	YES	18:10	
			10OCT2011	YES	7:00	YES	17:00	
			11OCT2011	YES	7:00	YES	16:50	
			12OCT2011	YES	7:00	YES	16:55	
			13OCT2011	YES	7:00	YES	17:10	
			14OCT2011	YES	7:00	YES	17:00	
			15OCT2011	YES	7:15		18:20	
			16OCT2011	YES	7:20	YES	18:10	
			17OCT2011	YES	7:00	YES	17:45	
			18OCT2011	YES	7:00	YES	17:40	
			19OCT2011	YES	7:00	YES	17:55	
			20OCT2011	YES	7:00	YES	18:05	
			21OCT2011	YES	7:00	YES	16:50	
			22OCT2011	YES	7:20	YES	18:25	
			23OCT2011	YES	7:15	YES	18:10	
			24OCT2011	YES	7:00	YES	16:55	
			25OCT2011	YES	7:00	YES	17:05	
			26OCT2011	YES	7:00	YES	17:00	
			27OCT2011	YES	7:00	YES	17:10	
			28OCT2011	YES	7:00	YES	17:20	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	29OCT2011	YES	7:20	YES	17:50	
			30OCT2011	YES	7:10	YES	18:05	
			31OCT2011	YES	7:20	YES	17:30	
			01NOV2011	YES	7:00	YES	17:00	
			02NOV2011	YES	7:00	YES	16:50	
			03NOV2011	YES	7:00	YES	17:05	
			04NOV2011	YES	7:00	YES	17:50	
			05NOV2011	YES	7:15	YES	18:05	
			06NOV2011	YES	7:05	YES	17:45	
			07NOV2011	YES	7:00	YES	16:50	
			08NOV2011	YES	7:00	YES	17:05	
			09NOV2011	YES	7:00	YES	16:50	
			10NOV2011	YES	7:00	YES	16:45	
			11NOV2011	YES	7:00	YES	17:05	
			12NOV2011	YES	7:15	YES	17:30	
			13NOV2011	YES	7:20		17:50	
			14NOV2011	YES	7:00	YES	16:55	
			15NOV2011	YES	7:00		17:10	
			16NOV2011	YES	7:15	YES	18:05	
			17NOV2011	YES	7:00	YES	17:00	
			18NOV2011	YES	7:00	YES	17:20	
			19NOV2011	YES	7:20	YES	17:15	Kann sich nicht mehr allein aus- und anziehen.
			20NOV2011	YES	7:10	YES	17:40	
			21NOV2011	YES	6:50	YES	16:55	
			22NOV2011	YES	6:50	YES	17:00	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	23NOV2011	YES	6:50	YES	17:20	
			24NOV2011	YES	6:50	YES	17:30	
			25NOV2011	YES	6:50	YES	17:20	
			26NOV2011	YES	7:10	YES	17:50	
			27NOV2011	YES	7:10	YES	17:30	
			28NOV2011	YES	6:50	YES	17:20	
			29NOV2011	YES	6:50	YES	17:35	
			30NOV2011	YES	6:50	YES	17:20	
			01DEC2011	YES	6:50	YES	17:30	
			02DEC2011	YES	6:50	YES	17:25	
			03DEC2011	YES	7:15	YES	17:40	
			04DEC2011	YES	7:15	YES	17:45	
			05DEC2011	YES	6:50	YES	17:10	
			06DEC2011	YES	6:50	YES	17:10	
			07DEC2011	YES	6:50	YES	16:55	
			08DEC2011	YES	6:50	YES	17:25	
			09DEC2011	YES	6:50	YES	17:20	
			10DEC2011	YES	7:10	YES	17:50	
			11DEC2011	YES	7:15	YES	17:40	
			12DEC2011	YES	6:20	YES	17:10	
			13DEC2011	YES	6:50	YES	17:00	
			14DEC2011	YES	6:50	YES	17:25	
			15DEC2011	YES	6:50	YES	17:05	
			16DEC2011	YES	6:50	YES	17:30	
			17DEC2011	YES	7:10	YES	18:05	

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Listing 16.2.10.4: Diary entries

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13FEB2013

Treat- ment	Random No.	Site ID	Date	Morning dose	Time	Evening dose	Time	Comment
Placebo	088	16	18DEC2011	YES	7:20	YES	17:50	
			19DEC2011	YES	6:15			

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Listing 16.2.10.5: End of study information

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13FEB2013

Treat- ment	Random No.	Site ID	Study com- pleted	Date of with- drawal	Date of last IMP intake	Date of last sub- ject data collected	Reason for withdrawal	Date of death	Cause of death	Double blind code broken
ACI-91	002	1	YES		22APR2010	20MAY2010				NO
	004	1	NO	15OCT2009	15OCT2009	29OCT2009	CONSENT WITHDRAWN			NO
	006	2	YES		23FEB2011	24MAR2011				NO
	010	1	NO	07NOV2009	06NOV2009	20NOV2009	CONSENT WITHDRAWN			NO
	012	1	YES		12JUL2011	18AUG2011				NO
	014	4	YES		28OCT2010	02DEC2010				NO
	015	4	YES		21FEB2011	22MAR2011				NO
	017	5	YES		03AUG2010	07SEP2010				NO
	019	5	YES		07DEC2010	12JAN2011				NO
	023	4	YES		18JUL2011	11AUG2011				NO
	027	20	YES		25OCT2011	01DEC2011				NO
	030	8	YES		14MAR2011	11APR2011				NO
	032	8	NO	07FEB2011	07FEB2011	07FEB2011	PATIENT NON-COMPLIANCE			NO
	033	9	YES		10NOV2010	06DEC2010				NO
	042	12	YES		11JAN2011	02MAR2011				NO
	043	12	NO	11AUG2010	11AUG2010	17SEP2010	ADVERSE EVENT	12AUG2010	ASPIRATION PNEUMONIA	NO
	046	11	YES		12JAN2011	15FEB2011				NO
	048	11	YES		16NOV2011	09JAN2012				NO
	050	21	YES		24OCT2011	15DEC2011				NO
	052	21	YES		24OCT2011	21NOV2011				NO
	055	5	NO	28APR2010	30MAR2010	28APR2010	ADVERSE EVENT			NO

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Listing 16.2.10.5: End of study information

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13FEB2013

Treat- ment	Random No.	Site ID	Study com- pleted	Date of with- drawal	Date of last IMP intake	Date of last sub- ject data collected	Reason for withdrawal	Double blind code broken
ACI-91	057	1	NO	08APR2011	06APR2011	08APR2011	CONSENT WITHDRAWN	NO
	066	16	NO	21DEC2010	21DEC2010	09FEB2011	ADVERSE EVENT	NO
	067	16	NO	31DEC2010	31DEC2010	08MAR2011	ADVERSE EVENT	NO
	071	18	YES		17NOV2011	05DEC2011		NO
	080	13	NO	01JUN2011	04MAR2011	01JUN2011	ADVERSE EVENT	NO
	081	17	YES		24OCT2011	22NOV2011		NO
	083	17	YES		09NOV2011	06DEC2011		NO
	087	16	YES		28NOV2011	28DEC2011		NO
	089	5	YES		14NOV2011	14DEC2011		NO
	093	17	YES		06DEC2011	28DEC2011		NO
	097	12	NO	16FEB2011	16FEB2011	20FEB2011	CONSENT WITHDRAWN	NO
Placebo	001	1	YES		08APR2010	06MAY2010		NO
	003	1	NO	04FEB2010	04FEB2010	04FEB2010	CONSENT WITHDRAWN	NO
	005	2	YES		02JUN2010	08JUL2010		NO
	009	1	YES		03SEP2010	01OCT2010		NO
	011	1	YES		26NOV2010	31MAR2011		NO
	013	4	YES		16SEP2010	20OCT2010		NO
	016	4	YES		28FEB2011	07APR2011		NO
	018	5	YES		22NOV2010	22DEC2010		NO
	020	5	NO	24FEB2010		25FEB2010	CONSENT WITHDRAWN	NO
	024	4	YES		07AUG2011	12SEP2011		NO
	028	20	YES		24NOV2011	20DEC2011		NO
	029	8	YES		01FEB2011	23FEB2011		NO

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Listing 16.2.10.5: End of study information

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13FEB2013

Treat- ment	Random No.	Site ID	Study com- pleted	Date of with- drawal	Date of last IMP intake	Date of last sub- ject data collected	Reason for withdrawal	Double blind code broken
Placebo	031	8	YES		17MAY2011	14JUN2011		NO
	034	9	YES		15MAR2011	20APR2011		NO
	041	12	YES		06OCT2010	04NOV2010		NO
	044	12	YES		01DEC2010	03MAR2011		NO
	045	11	YES		15DEC2010	17JAN2011		NO
	047	11	YES		27JUL2011	29AUG2011		NO
	049	21	NO	08SEP2011	08SEP2011	24NOV2011	ADVERSE EVENT	NO
	051	21	YES		25OCT2011	22NOV2011		NO
	056	5	YES		19APR2011	24MAY2011		NO
	058	1	YES		13DEC2011	10JAN2012		NO
	059	1	YES		08DEC2011	12JAN2012		NO
	065	16	NO	16MAR2011	16MAR2011	21OCT2011	ADVERSE EVENT	NO
	068	16	YES		28NOV2011	09JAN2012		NO
	069	23	YES		14DEC2011	11JAN2012		NO
	072	18	YES		15DEC2011	17JAN2012		NO
	079	13	YES		21JUN2011	19JUL2011		NO
	082	17	YES		12OCT2011	24NOV2011		NO
	084	17	YES		22NOV2011	15DEC2011		NO
	086	21	YES		25OCT2011	22NOV2011		NO
	088	16	YES		19DEC2011	28FEB2012		NO

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